Reference Manual

AU680 Chemistry Analyzer

CE IVD

B63185AA
July 2015

Beckman Coulter, Inc.
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BECKMAN COULTER

Reference Manual
AU680 Chemistry Analyzer
PN B63185AA (July 2015)

Trademarks

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Rx Only
Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

Initial Issue, B63185, 08/2015

Software version 4.0

This document was created to:

- Add the Principle of the Realtime Water Blank Check section.
- Update the Auto Power On Screen section.
- Add the Lipemia, Icterus, and Hemolysis (LIH) section.
- Update the Review and Delete Reagent History section.
- Add the Order (Requisition) and Sample Analysis section.

Revision History

Safety Notice

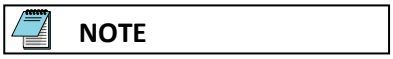
Read all product manuals and consult with Beckman Coulter trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Beckman Coulter.

Alerts for Warning, Caution, Important, Note, and Tip

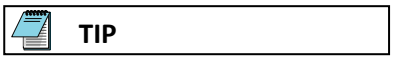
Warning indicates a potentially hazardous situation which, if not avoided, could cause death or serious injury. Warning can indicate the possibility of erroneous data that could cause an incorrect diagnosis.

Caution indicates a potentially hazardous situation which, if not avoided, can cause minor or moderate injury. Caution can also alert against unsafe practices, or indicate the possibility of erroneous data that could cause an incorrect diagnosis.

Important indicates important information to follow.



Note indicates notable information to follow.



Tip indicates information to consider.

Summary of Hazards

This section describes the possible hazards of the system. The hazards of individual procedures in this manual are included in the warnings or cautions within the instructions. Read this section before you operate this system.

Follow the power requirements in the system specifications. Follow the procedures and safety warnings throughout this manual.

If you use the system in a manner not specified by Beckman Coulter, the protection provided by the system can be impaired and incorrect results or system failure can occur.

Bar Code Reader

Do not adjust or remove the housing of any bar code reader. The bar code readers use lasers and looking directly at the laser light can be hazardous. Assume that the laser is always on.

Biohazardous and Chemical Materials

Observe all biohazard precautions when doing maintenance, service, or troubleshooting on the system. Biohazard precautions include, but are not limited to, wearing gloves, eye shields, and lab coats, and washing hands after working on contaminated portions of the system.

Follow all laboratory procedures and policies for handling infectious and pathogenic materials.

Avoid skin contact with reagents and other chemical preparations. Wear Personal Protective Equipment (PPE) to work with reagents and other chemical preparations used with the system. For more information, refer to the related SDS (Safety Data Sheet).

Clean spills of biohazardous or other potentially hazardous substances on the system immediately. If the system must be decontaminated, contact Beckman Coulter.

Follow your laboratory procedure for biohazardous and hazardous material disposal.

Electric Shock

Do not replace or service any components where you can contact hazardous parts that could cause electric shock. Beckman Coulter must perform this maintenance.

Electrical Ground

Never operate the system until the power cord is connected correctly to an electrical ground.

Use a three-pronged (grounded) power cord to connect the system to a matching three-wire grounded outlet. Do not use an adapter to connect the power plug to a two-pronged outlet.

Electromagnetic Wave and Noise

The system generates, uses, and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference between the system and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Move the equipment so there is a greater distance between the equipment and the system.
- Reorient the equipment in relationship to the system.
- Confirm that the equipment is operating from a different power service connector than the power service connector for the system.
- Do not use mobile or cordless telephones and transceivers in the same room as the system.
- Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the system.

Flammable Materials

Do not use this system near flammable materials.

Moving Parts

While the system is in operation, do not touch or go close to any moving parts. Close protective guards and covers during operation. Failure to close covers correctly can cause injury or incorrect results.

Liquid Waste

Handle all liquid waste as potentially infectious.

Some liquid waste can require special treatment before disposal. Follow your laboratory procedure.

Some substances in the reagents, control materials, calibrators, and wash solutions have disposal regulations. Follow your laboratory procedure.

Solid Waste

Handle all solid waste as potentially infectious.

Some solid waste can require special treatment before disposal. Follow your laboratory procedure.

Handle any used or replaced parts (such as tubes, mix bars, probes, cuvettes, and wash nozzles) as infectious waste materials. Follow your laboratory procedure.

AU680 Hazards

- A Beckman Coulter representative installs the system. If the system installation needs modification, contact Beckman Coulter.
- If the system malfunctions, power off the system completely using the main breaker located on the left side of the analyzer before any repair service.
- If fluid is spilled on the system, turn off the main breaker located on the left side of the analyzer immediately. Wipe up the spill only after turning off the main system breaker. If fluid enters the system after a spill, contact Beckman Coulter before restarting the analyzer.

- After transferring the analysis results to a laboratory information system, confirm that the sample numbers and sample IDs are correct.
- Substances such as Lipemia, Icterus, and Hemolysis can interfere with results. Refer to the reagent IFU for specific substance interference information.
- To be sure the analytical data is accurate:
  - Confirm the quality of deionized (DI) water is within specifications.
  - Confirm that all tests have passed calibration, and calibration is not expired.
  - Inspect the quality control data.
- Use the correct reagent, calibrator, and control to analyze samples.
- Avoid excessive reagent agitation, which can cause bubbles. If bubbles are visible on the surface of the reagent, remove them. Confirm that the reagent bottles are placed securely on the reagent tray with the correct adapters and partitions. If the bottles are tilted, incorrect results can occur, or you can damage the reagent probe.
- Prepare reagents, wash solutions, calibrators, and QC samples according to the Instructions for Use (IFU), paying particular attention to any reconstitution, mixing, and pretreatment instructions.
- Handling samples:
  - Sample to sample carryover is one potential source of analytical error in the clinical laboratory. Do not use the same sample run on an AU Chemistry system for analysis of analytes for which a small quantity of carryover could cause problems with the results.
  - This system analyzes serum, urine, plasma, other sample types, and whole blood (for HbA1c only). Other refers to other body fluids such as cerebrospinal fluid (CSF). Some samples cannot be analyzed depending on the analysis test, reagent, and sample tubes used. For questions regarding reagent and sample tube type, contact Beckman Coulter.
  - Use serum or plasma that is clot free, or urine that is free from suspended matter. If serum or urine contains clots or suspended matter, the probe can clog and cause problems with the analysis results.
  - Chemicals present in the sample (medicine, anticoagulant, preservative, and so on) can significantly interfere with the results.
  - Highly viscous samples can interfere with the testing of the samples and the reliability of data.
  - Refer to the Instructions for Use (IFU) for each test for correct sample collection and storage. Incorrect storage of samples can alter the analyte in a sample.
  - Use only sample containers and sample tubes specified by Beckman Coulter.
  - To reduce the risk of interference, centrifuge and then separate serum and plasma samples adequately from blood cells immediately. Before analysis, confirm that samples are free from suspended matter, such as fibrin. While the system has a sophisticated clot detection mechanism, this mechanism is not able to detect all clots. Carefully inspect the samples.
  - Collect urine samples using correct preservatives and remove any suspended matter using centrifugation before analysis (CLSI GP16-A2).
  - Confirm that any anticoagulants or collection devices that employ a barrier are compatible with the test reagent being used. Refer to the Instruction for Use for suitable and validated sample types. Use caution when using sample tubes containing barriers or gels. Confirm the suitability of all collection devices in use.
  - For information about whether a serum separating agent is correct or not, contact the chemical reagent manufacturer or distributor.

  - When using sample containers or tubes containing a separating medium, confirm that there is enough serum to avoid contaminating or blocking the sample probes with the separating medium.
  - Confirm that there is enough sample for correct sampling to occur. The small amount of wash water left on the sample probe can dilute the volume of sample left in the sample tube.
- To prevent water leaks, confirm that Beckman Coulter has fitted water supply and drainage hoses according to local guidelines.
- To confirm system performance, maintain and inspect the system periodically by replacing the parts according to the instructions in this guide.
  - Have and follow a maintenance schedule for this system.
  - Create a maintenance routine for the computer software and hardware, including frequent backing up of data containing analysis settings, results history, and the alarm log list file.
  - Do not store backups onsite. Keep one copy on-site for reference and one copy offsite.
- Before using the system for the first time, set parameters for the reagent and sample quantity, measurement wavelength, calibrator values, and so on. Enter test specific parameters from the chemistry setting sheet to have optimum system performance. Enter any updates to these settings into the system immediately.
- Dedicate the computer hardware to only running the system software. Do not connect the computer hardware to the Internet, unless instructed to do so by Beckman Coulter.
- Keep the analyzer covers closed except for startup procedures and maintenance. If the covers are open for extended periods of time, excess condensation can be generated in the reagent refrigerators and cause errors.

AU680 Hardware Labels

The following hardware labels are attached to the AU680. Use caution, observe, and follow all warning labels. Do not cover or remove these labels. If the labels peel off or become illegible, contact Beckman Coulter to replace the labels. Orange labels indicate that there is a risk of Serious Injury. Yellow labels indicate that there is a risk of Personal Injury, Fire, or Damage.

Electric Shock Label

This symbol indicates an area of the system that should not be accessed under any circumstances, due to risk of electrical shock. (Labeling Position: near the inlet of the power code on the left side of the analyzer.)

High Temperature Danger Label

This symbol indicates the risk of burning by touching the hot photometer lamp directly when replacing it. (Labeling Position: near the light source lamp.)

Biohazard Label

This symbol indicates the use of biohazardous material. Wear protective clothing and follow universal precautions as dictated by local or national regulations (CLSI GP17-A2, ISO15190 or 29CFR 1910.1030).

Risk of biohazardous materials such as sample probes, mix bars, sample rack, wash nozzle component, cuvette, sample probe wash well, condensed waste liquid drain hole, ISE sample pot, ISE roller pump tubing, drain hole, and so forth. (Labeling Position: On the surface of the analyzer and the rear cover.)

Laser Radiation Label

CLASS 1 LASER PRODUCT complies with IEC60825-1. (Labeling Position: near the main switch on the left side of the analyzer.)

CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM. (Labeling position: near the interlock switch of the rack feeder module, near the interlock switch of the large STAT cover, and near the small STAT cover).

CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM. (Labeling Position: near the sample ID barcode reader window for the STAT table and rack feeder module.)

Personal Injury Label

This symbol indicates areas where a risk of injury due to system movement is possible. Fingers or other body parts should be kept clear of these areas during system operation.

- Danger of injury by moving parts of the sample probe, reagent probes, mix bars, wash nozzle component, and so forth. (Labeling Position: on the analyzer surface and rear cover.)
- Danger of injury by operation parts of syringe. (Labeling Position: near the sample, reagent, and wash syringes.)
- Danger of injury by moving parts, for example the Wash Solution roller pump, and so forth. (Labeling Position: near the Wash Solution roller pump or other moving part.)
- Danger of injury by moving parts, for example the ISE roller pump, and so forth. (Labeling Position: back of the ISE cover)

Danger Label

Indicates a potentially hazardous situation which, if not avoided, could result in operator's injury and/or serious physical damage.

- Danger of leak from water supply and discharge component. (Labeling Position: near the water outlet)
- To avoid electrical shock, do not remove the cover connector screws to access the water supply component. (Labeling Position: near the power outlet of water supply component (option).)
- Do not lean against the PC rack component (option), which could result in it falling down. (Labeling Position: near the keyboard for the PC rack component.)

Recycling Label

This label is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this label indicates that:

1. the device was put on the European Market after August 13, 2005 and
2. the device is not to be disposed of via the municipal waste collection system of any member state of the European Union

Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or local Beckman Coulter office for details on the take-back program that facilitates the correct collection, treatment, recovery, recycling and safe disposal of these products.

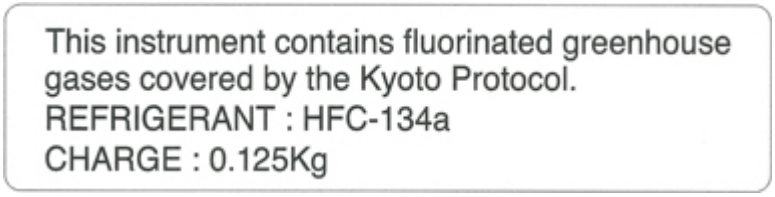
For the Japan Market:

This system is considered an industrial waste, subject to special controls for infectious waste. Prior to disposal of the system, refer to the "Waste Disposal and Public Cleaning Law" for compliance procedures.

C-Tick Mark Label

The C-Tick mark is intended for use on products that comply with the applicable Electromagnetic Compatibility (EMC) standards in the Australian or New Zealand market.

Fluorocarbons Recovery and Destruction Law Label



This product is a Class 1 product according to Fluorocarbons Recovery and Destruction Law.

This system uses a HFC (hydro fluorocarbon) cooling medium.

Chlorofluorocarbon (CFC) chemicals cannot be discharged indiscriminately. When the system is discarded, recover CFC chemicals.

The type and volume of the CFC chemicals are described on the refrigerator.

Restriction of Hazardous Substances (RoHS) Labels

These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

RoHS Caution Label

This logo indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture.

RoHS Environmental Label

This logo indicates that the product does not contain any toxic or hazardous substances or elements. The “e” stands for electrical, electronic and environmental electronic information products. This logo indicates that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and is environmental. The outer

circle indicates that the product can be recycled. The logo also signifies that the product can be recycled after being discarded, and should not be casually discarded.

For In Vitro Diagnostic Use Label

IVD

This symbol is for an in vitro diagnostic medical device.

AU680 System Display and Labels

Figure 1 On Switch

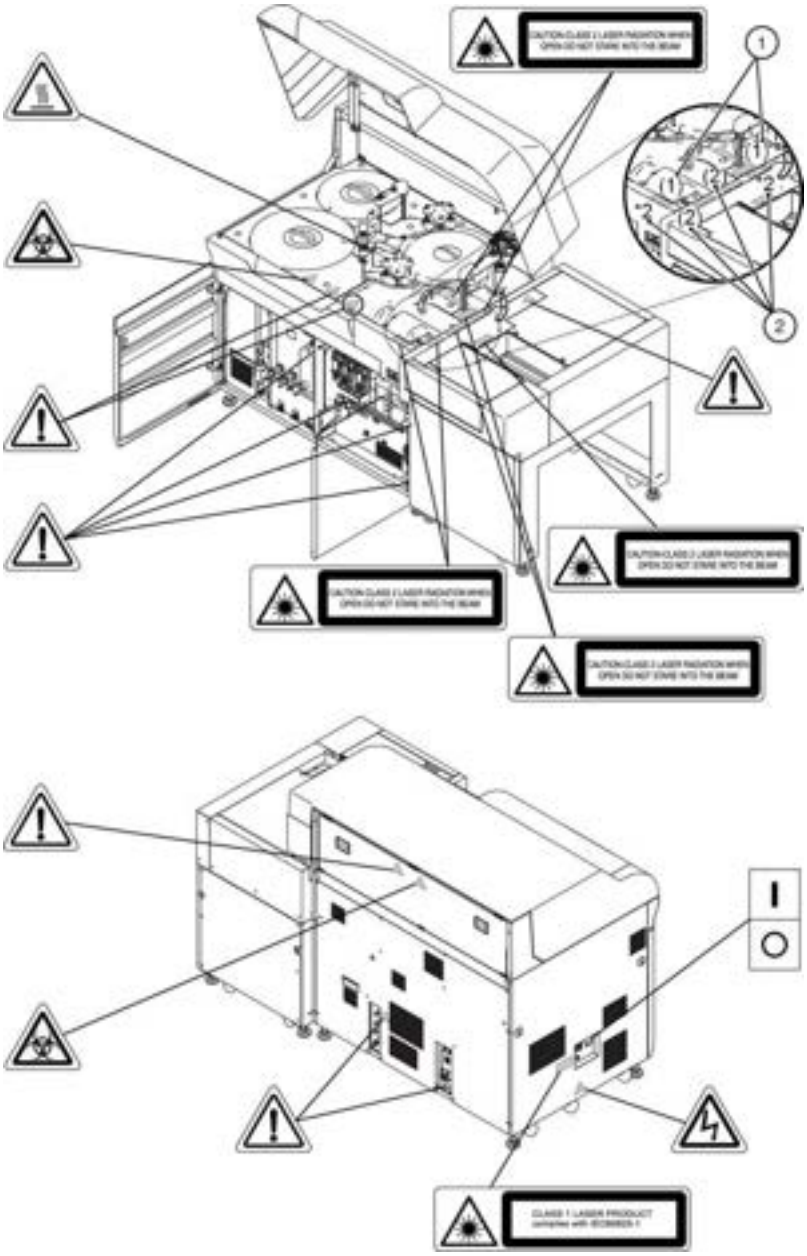
Figure 2 Off Switch

Figure 3 Ground Terminal

Labels

- Stripes - Orange stripes affixed to the system surface indicate the movement areas of the hardware components. Avoid these areas during operation.
- Warning Labels - Identify areas of the system where hazards exist and where caution should be taken to avoid serious injury or death.
- Instruction Labels - Instruction labels are affixed on the system at relevant locations to alert the operator to operate the system correctly.

Figure 4 AU680 Labels



1. The label is attached to the inside of the lid.
2. Early production AU680s had labels applied to the (2) positions. Subsequent AU680s have labels applied to the (1) positions.

Contents

CHAPTER 1

System Overview

Software Overview

Software Paths, Screens, and Tabs

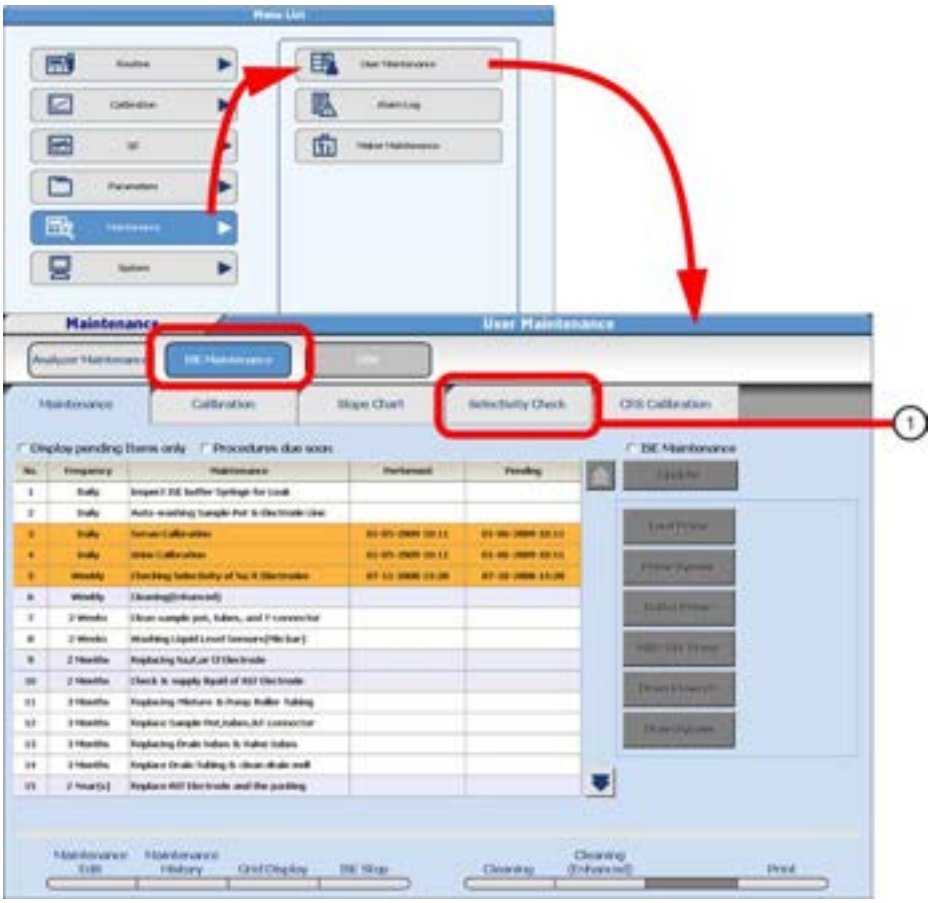
A software path is a sequence of options selected in the software interface in the order indicated.

Software paths in this manual are expressed as follows:

Select **Maintenance > User Maintenance > ISE Maintenance**.

Following this path, first select the **Maintenance** menu, then **User Maintenance**, and then **ISE Maintenance** on the resulting submenu.

Figure 1.1 Software Paths, Screens, and Tabs

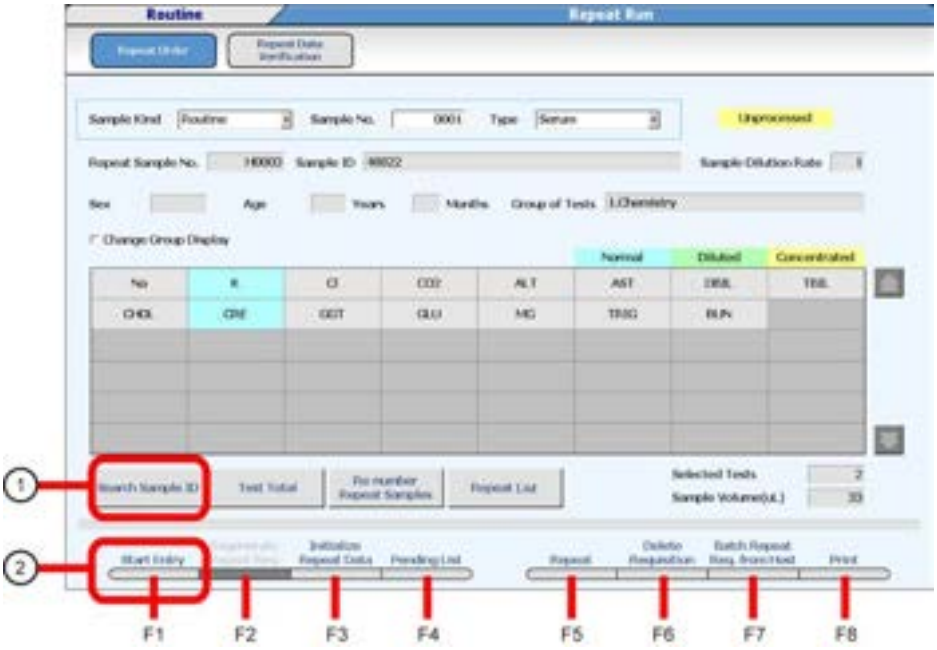


1. Selectivity Check tab

Software Buttons

All buttons that appear in the software interface are part of a single procedural step and appear in a **bold** font. Some software buttons have a corresponding function key that can be accessed from the keyboard. These buttons appear in **bold** font with the corresponding keyboard function number in parenthesis.

Figure 1.2 Example Software Buttons



1. Search Sample ID button
2. Start Entry (F1) button

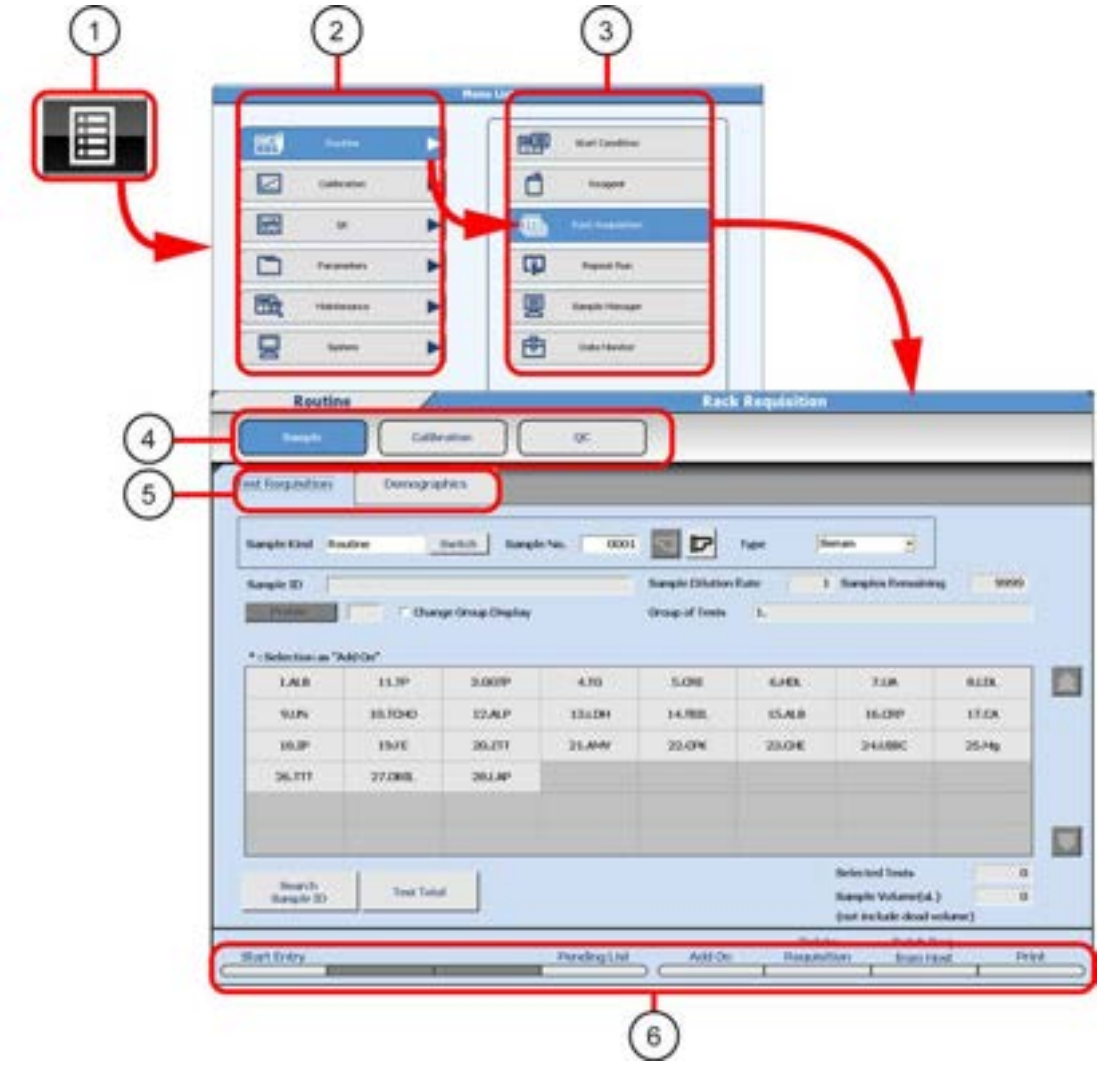
Menu List Organization and Outline

To set up the required parameters, access analysis information, and to check analysis results, select the appropriate menu and submenu category in the following order **Menu List > Menu > Submenu > Screen > Tab**.

The following example displays the pathway using the Rack Requisition Screen.

1	Select the **Menu List** button from the main button bar.
2	Select **Routine** from the menus.
3	Select **Rack Requisition** from the submenus.
4	Select **Sample** from the screens.
5	Select **Test Requisition** from the tabs.

Figure 1.3 Menu Path



1. Menu List
2. Menus
3. Submenus
4. Screens
5. Tabs
6. Buttons for corresponding function keys

TIP

Access **Menu List** from the main button bar in any menu.

Organization and Functional Outline of Routine Menu

Use this menu for various basic operational procedures.

Some menus require initial programming by your Beckman Coulter representative before you can use them.

Table 1.1 Routine Menu Options

Submenu	Screen
Start Condition	Used to program the index, Group of tests, operator name, and start sample numbers before you start analysis. Refer to the AU680 Instructions for Use.
Reagent	**Reagent Management** Used to check the quantity of reagent and the quantity of tests available in a bottle. Refer to AU680 Instructions for Use.
	Reagent Inventory A breakdown of the volume or tests of R1 and R2 (for each reagent) used for each day of the week for a specified timeframe. Refer to Reagent Inventory.
	Reagent Consumption A breakdown of reagent used for a specified timeframe by volume or tests of R1 and R2 by each rack type. Refer to Reagent Consumption.
Rack Requisition	**Sample** Used to order (requisition) patient samples manually (demographics and tests). Refer to the AU680 Instructions for Use.
	Calibration Used to order (requisition) calibrators. Refer to the AU680 Instructions for Use.
	QC Used to order (requisition) quality control samples. Refer to the AU680 Instructions for Use.

Table 1.1 Routine Menu Options (Continued)

Submenu	Screen
STAT Requisition	**STAT Status** Used to view the status of the STAT table and start STAT sample analysis. Refer to the AU680 Instructions for Use.
	Sample Used to perform priority STAT sample orders (requisitions) for STAT analysis on the STAT table. Refer to the AU680 Instructions for Use.
	Calibration Used to perform calibration orders (requisitions) for calibration analysis from the STAT table. Refer to the AU680 Instructions for Use.
	QC Used to perform QC orders (requisitions) for QC analysis from the STAT table. Refer to the AU680 Instructions for Use.
Repeat Run	**Repeat Order** Used to add, change, or delete repeat test orders (requisitions). Refer to the AU680 Instructions for Use.
	Repeat Data Verification Used to view repeat results with the original results and to overwrite data. Refer to Monitor Repeat Results.
Sample Manager	**Sample** Used to display analysis results, perform data correction, print a data list and batch transfer data online. • Refer to Edit Analysis Data. • Refer to the AU680 Instructions for Use.
	RB/CAL/QC Used to print and batch transfer RB/CAL/QC data. Refer to the AU680 Instructions for Use.

Table 1.1 Routine Menu Options (Continued)

Submenu	Screen
Data Monitor	**Reaction Monitor** Displays information about reaction processes of analysis results. Refer to Display Reaction Monitor.
	Data Statistics Displays key statistics of patient sample results and the results of a test within one index as bar charts. Refer to View Data Statistics.
	Correlation Chart Displays a correlation chart. Refer to Create a Correlation Chart.

Organization and Functional Outline of Calibration Menu

Use this menu to display a history of calibration information and perform calibration verification.

Table 1.2 Calibration Menu Options

Submenu	Screen
Calibration Monitor	View the current reagent blank and calibration status and a history of the reagent blank and calibration data on a graph. Refer to Monitor the Reagent Blank and Calibration.
Calibration Verification	**Calibration Verification** Confirms the calibration performance. Refer to Verify Calibration.
	Material Parameters Enter parameters for calibration verification and view or print a chart. Refer to Enter Material Parameters.

Organization and Functional Outline of QC Menu

Use this menu to display and edit the result and history of quality control.

Table 1.3 QC Menu Options

Submenu	Screen
QC Monitor	**Daily Chart** Displays the QC data variation within the same or between index dates as a daily chart. Refer to Monitor the QC Using the Daily Variation Chart.
	Day to Day Chart Displays the QC data variation within the same or between index dates as a day to day chart. Refer to Monitor the QC Using the Day-to-Day Variation Chart.
	Twin Plot Chart Displays the QC data variation of two QC samples as a twin plot chart. Refer to Monitor the QC Using the Twin Plot Chart.
QC Data Review	Used to edit QC result Refer to Edit Quality Control Data.

Organization and Functional Outline of Parameter Menu

Use this menu to program information for all tests. This information is required before running the system.

Program the parameters before running the analyzer for the first time.

Table 1.4 Parameter Menu Options

Submenu	Screen
Common Test Parameters	**Test Name** Program basic parameters such as test name and reagent ID. Refer to Test Name Screen.
	Profile Program profiles for samples, reagent blank, calibration, and QC. Refer to Profile Screen.
	Group of Tests Assigns tests to a Group. A maximum of three Groups of tests can be programmed. A maximum of 60 photometric tests and 3 ISE tests can be programmed in a Group. Refer to Group of Tests Screen.

Table 1.4 Parameter Menu Options (Continued)

Submenu	Screen
Specific Test Parameters	**General** Used to program detailed parameters for general test items. Refer to General Screen.
	LIH (Serum Index) Used to program detailed parameters for the Lipemia/Icterus/Hemolysis test. Refer to LIH Screen.
	ISE Used to program detailed parameters for the ISE tests. Refer to ISE Screen.
	HbA1c Used to program detailed parameters for the Whole Blood HbA1c test. Refer to HbA1c Screen.
	Calculated Tests Used to program detailed parameters for calculated tests. Refer to Calculated Tests Screen.
	Range Used to program parameters for the reference range. Refer to Range Screen.
Repeat Parameters[1]	**Repeat Common** Used to program the common parameters for a repeat run analysis. Refer to Repeat Common Screen.
	Repeat Specific Used to program the repeat and reflex decision ranges and the repeat dilution rate of repeat run analysis for individual tests. Refer to Repeat Specific Screen.

Table 1.4 Parameter Menu Options (Continued)

Submenu	Screen
Calibration Parameters	**Calibrators** Used to program common calibrator parameters such as name, ID and lot number. Refer to Calibrators Screen.
	Calibration Specific Used to program specific calibration parameters for individual tests. Refer to Calibration Specific Screen.
	STAT Table Calibration Used to program parameters for calibration analysis using the STAT Table.
QC Parameters	**Controls** Used to program the common parameters for a quality control analysis. Refer to Controls Screen.
	QC Specific Used to program the mean value and standard deviation for quality control. Refer to QC Specific Screen.
	STAT Table QC Used to program parameters for QC analysis using the STAT Table.
Misc	**Checked Tests** Used to program parameters for logic checked tests. Refer to Checked Tests Screen.
	Contamination Parameters Used to program parameters to prevent contamination of tests. Refer to Contamination Parameters Screen.
	Data Check Parameters Used to program parameters for data check such as diagnosis of prozone. For more information, contact Beckman Coulter. Refer to Data Check Parameters Screen.

Table 1.4 Parameter Menu Options (Continued)

Submenu	Screen
1. When the AU680 is connected to a laboratory automation system, repeat run parameters are determined from the laboratory information system, not the AU680 Repeat Parameters.	

Organization and Functional Outline of Maintenance Menu

Use this menu to monitor analyzer and ISE maintenance, review a detailed alarm log, and perform diagnostic functions.

Table 1.5 Maintenance Menu Options

Submenu	Screen
User Maintenance	**Analyzer Maintenance** Displays the maintenance schedule and perform maintenance procedures. Refer to the AU680 Instructions for Use.
	ISE Maintenance Displays the maintenance schedule of the ISE module and perform ISE maintenance procedures. Refer to the AU680 Instructions for Use.
	PROService Displays the connection status of Beckman Coulter PROService and transmits the AU680's various files. For more information, refer to Using Beckman Coulter PROService (Option).
	Load Reagent Parameters Loads Specific Test Parameters and Calibration Specific parameters from a CD.
Alarm Log	Chronologically lists the alarms that have occurred.

Table 1.5 Maintenance Menu Options (Continued)

Submenu	Screen
Maker Maintenance	**Program Version** Displays DPR program, PROService and Help version and revision, and program version, revision, and station ID of the analyzer.
	Analyzer Diag Checks each analyzer component for abnormal conditions. Some checks should only be performed by Beckman Coulter.
	ISE Diag This screen contains the following major operations. Some checks should only be performed by Beckman Coulter. • Checks the ISE component for any abnormal conditions. • Performs calibration and sample measurement. • Performs Buffer, MID/REF, or Total Primes.

Organization and Functional Outline of System Menu

Use this menu to program online conditions, list formats, comments, bar code options, various system settings, and data management.

Table 1.6 System Menu Options

Submenu	Screen
Online	Used to program the parameters for online communication between a laboratory information system and the AU680. Refer to Online Menu.
Format	**Requisition Format** Used to enter the sample order (requisition) parameters. Refer to Format Menu.
	List Format Used to program the common format parameters for printing the pending list, work list, repeat list and the data list. Refer to Print Formats.
Comment Masters	Used to customize the comments appended to the analysis results. Refer to Comment Masters Menu.

Table 1.6 System Menu Options (Continued)

Submenu	Screen
System Condition	**Analysis mode** Used to program the analysis mode, bar code definition, auto or manual repeat and other system parameters. Refer to Analysis Mode Screen.
	Set Date and Time Used to program the system date and time. Refer to Set Date and Time Screen.
	Auto Power On Used to program the auto power on time for each day of the week. Refer to Auto Power On Screen.
	Password Used to program and change passwords. Refer to Program a New User Name and Password.
	Login Condition Used to program login information. Refer to Login Condition and Password Screens.
User Menu	Used to add a menu to the User Menu button on the main button bar. Refer to User Menu.
Data Management	**External Data Management** Saves the analysis data on an external storage device or media. Refer to Save Data to External Media.
	File Management Used to save and up load parameter files on an external storage device or media. Refer to Save or Load Parameters.
	Offline Format Used to program the output format of results and save data in a delimited format for use in external applications (spreadsheets, and so on). Refer to Offline Criteria.

User Menu Overview

The User Menu allows you to select the required menu for direct access.

The User Menu displays the following:

- A customized (operator-defined) list of common menus.
- Customize (operator-defined) menu names.

Figure 1.4 User Menu

- The User Menu function allows the selection of up to 16 menus most frequently used by the operator.
- User-defined menu names can be programmed.

How to Use Operation Help

View PDF files using the Adobe Reader software.

Figure 1.5 Using Buttons in Adobe Reader

1. Search for information by entering a search string
2. Browse from one page to another
3. Zoom in and out
4. Maximize and resize

Major features of the Adobe Reader software include:

- Search for information by entering a search topic.

  Select the binoculars symbol. Enter the search topic or word and select search.
- Browse from one page to another.

  Use the Next Page and Previous Page buttons at the bottom of the window.
- Zoom in and out.

  Use either the plus or minus button to the left and right of the percentage reading or select the magnifier and then select the page. To decrease the size of the page, select the minus magnifier.
- Maximize and resize.

  To resize the reader window (for example to make it smaller), select the Restore Down button in the top right-hand corner of the window. Position the cursor at the edge of the window and when it changes to a double-ended arrow, drag the borders of the window to the desired size. As the border is dragged, the size of the document automatically zooms allowing more text to become readable.

  To expand the window to fit the full size of the window again, select the Maximize button.
- Close the Adobe Reader.

  To close the PDF file when finished using it, select the Close button in the top right-hand corner of the Reader window.

Principles of Analysis

This system performs automated analysis of serum, urine, other fluids, and whole blood. It measures sample components and automatically generates results.

This section provides an overview of how the AU680 tests samples. It also describes the ISE measuring method.

Reagent Blank

To calculate a measurement value (reaction OD), the reagent blank OD (reagent OD at each photometric point of P0 to P27) and the Deionized (DI) water blank OD values (photocal data) are subtracted from the measured OD of a sample reacted with a reagent.

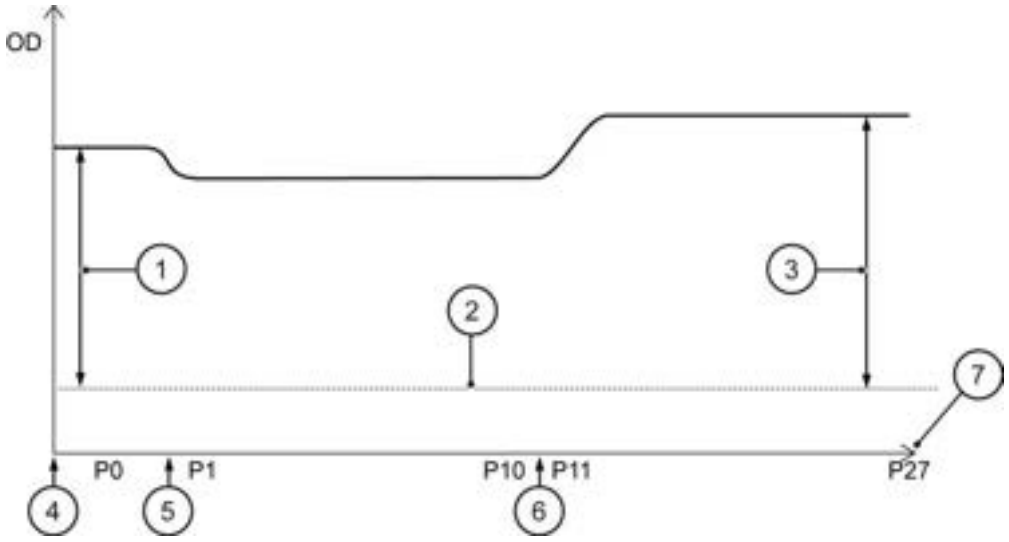
By performing a reagent blank measurement, the reagent blank OD values (RB) at all photometric points shown in the following chart can be obtained.

Reagent blank is measured using the blue rack. Position 1 and position 2 of the blue racks can be programmed for serum, urine, other-1, other-2, and whole blood in **Parameters > Calibration Parameters > Calibrators**. Typically, position 1 is programmed for serum, urine, other-1, other-2, and whole blood, and position 2 is not used. Place the sample (deionized water) in position 1 of the blue rack.

The system measures up to four replicates of the sample and determines the reagent blank data (reagent blank OD value).

1 replicate: OD value.
2 replicates: Mean value of two OD values.
3 replicates: Mean value of two closest OD values.
4 replicates: Highest and lowest OD values are discarded and the two remaining OD values are averaged.

Figure 1.6 Reagent Blank (Compared with water blank; example of 2 step analysis)



1. Reagent OD value at the first point (first data)
2. Deionized water blank (photocal data)
3. Reagent OD value at the last point (second data)
4. R1 (first reagent) dispensing
5. Sample (water) dispensing
6. R2 (second reagent) dispensing
7. Photometric point

The following describes the first point reagent OD value (first data) and last-point reagent OD value (second data).

First point reagent OD value (first data)

- First point reagent OD value (RB) = {first point measured OD value} -{DI water blank (photocal data)}.
- If the first point reagent OD value is outside the reagent OD range that was programmed in **Parameters > Specific Test Parameters > Reagent OD Limit First**, a flag y (for over range) or u (for under range) is added to the data.

Last point reagent OD value (second data)

- Last point reagent OD value (RB) = {last point measured OD value} - {DI water blank (photocal data)}.
- If the last point reagent OD value is out of the reagent OD range that was programmed in **Parameters** > **Specific Test Parameters** > **Reagent OD Limit Last**, a flag Y (for over range) or U (for under range) is added to the data.

End Point Assays

1-point Assay

This is a general end point assay that determines the reaction mixture OD from the OD measured at a specified photometric position.

Reaction mixture OD = OD (at specified position) - OD0 (at position 0)

Figure 1.7 Reaction Curve for 1-point End Point Assay

2-point Assay (Self-Blank Method)

This is for an end point assay that requires a sample blank adjustment. The OD values before dispensing the reagent 2 should be eliminated as the blank channel. The OD values of the blank channel are subtracted from those measured after dispensing the reagent 2 to obtain correct data without influences from turbidity or color of the serum.

The OD value in this assay is given by the following expression:

K2 = {R1. V / (R1.V + R2.V + S.V)}

K3 = {(R1.V + S.V) / (R1.V + R2.V + S.V)}

Reaction OD value = (Px - K2 × P0) - (K3 × Pz - K2 × P0).

This calculation result is defined as the reaction OD value.

Figure 1.8 Reaction Curve for 2-Point End Point Assay (Self-Blank Method)

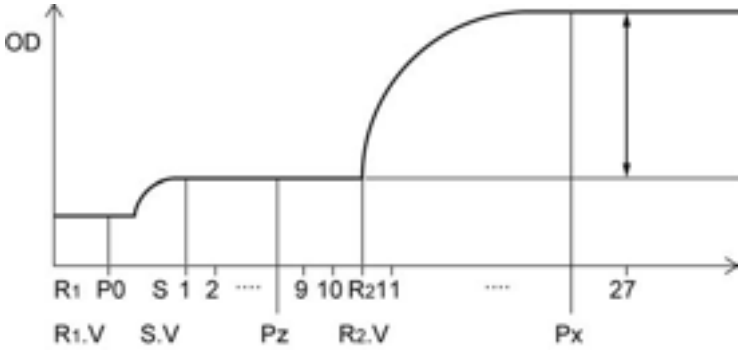


Table 1.7 2-point Assay (Self-Blank Method)

Item	Description
R1.V:	Reagent 1 dispense volume
R2.V:	Reagent 2 dispense volume
S.V:	Sample dispense volume
P0:	OD value at the first point
Pz:	OD value before dispensing reagent 2
Px:	OD value after dispensing reagent 2

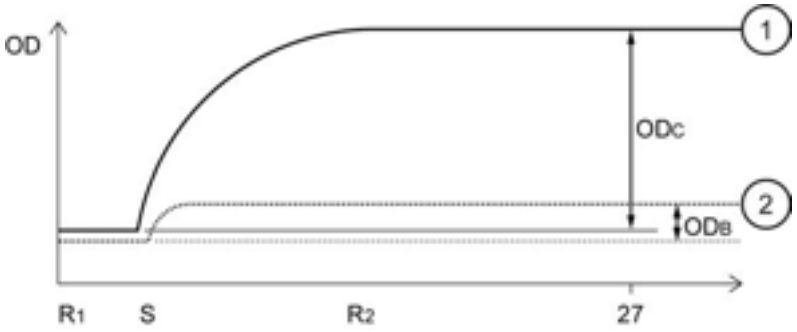
End Assay (Sample Blank Correction)

Two cuvettes are used in this type of assay, a cuvette for the color reaction and a cuvette for the sample blank. Blank item OD values, which include serum quality issues, are measured first. Then, the blank item value is subtracted from the measured OD value of the actual sample (OD value of the color item).

With this end assay (sample blank correction), higher accuracy data can be obtained than the 2-point assay even when serum quality issues (dotted line in the figure below) are unavoidable.

Reaction OD value = [Color item OD value (OD_C)] - [Blank item OD value (OD_B)]

Figure 1.9 Reaction Curve for End Point Assay (Sample Blank Correction)



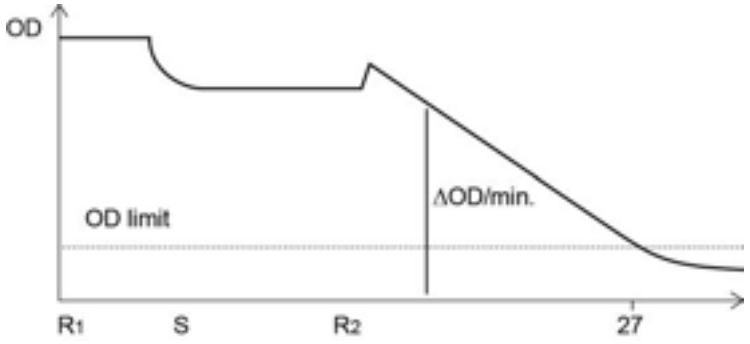
1. Color reaction channel
2. Sample blank channel

Rate Assays

Rate Assay

This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method.

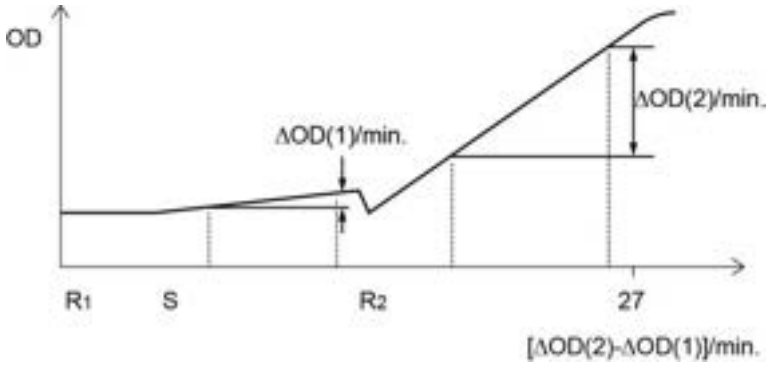
Figure 1.10 Reaction Curve for Rate Assay



Double Rate Assay

This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method. Next, the system obtains the OD rate of the objective substance from the calculation expression.

Figure 1.11 Reaction Curve for Double Rate Assay

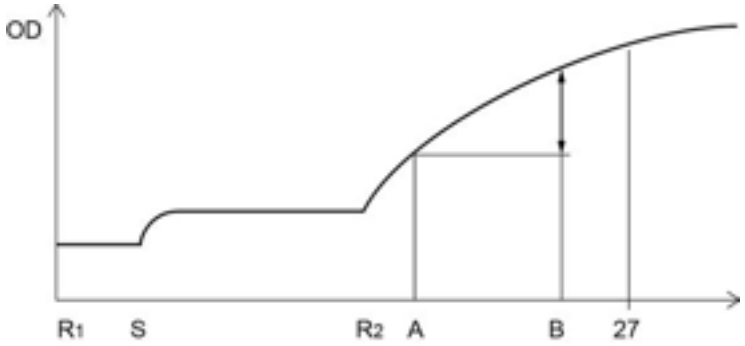


Fixed Point Assay

A fixed point assay measures the OD value at two specified photometry points. The two photometry points are measured after the beginning of reaction between sample and reagent.

Reaction OD value = OD_B - OD_A

Figure 1.12 Reaction Curve for Fixed Point Assay



Quality Control

A wide variety of quality control techniques are available to monitor analyzer accuracy.

The analyzer software has single rule, multi rule, and twin plot QC evaluation.

- Single rule is the most commonly used technique
- Use multi rule to prevent notification of insignificant errors
- Use twin plot for easier classification of systematic and random errors

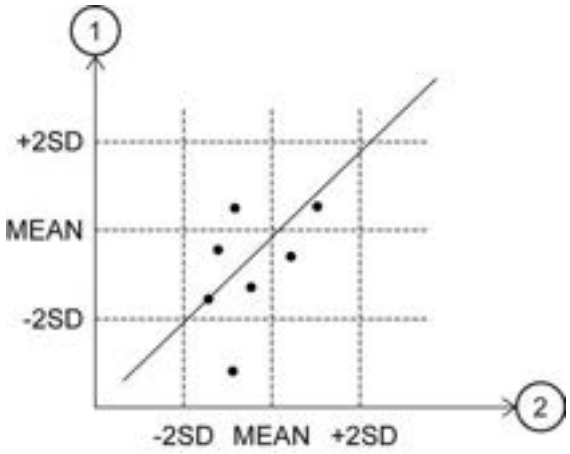
For more information, refer to Monitor QC.

The following describes the twin plot control and multi-rule control.

Twin Plot Control

Evaluate quality controls with normal level expected values and abnormal level expected values together.

Figure 1.13 Twin Plot Chart



1. Abnormal control
2. Normal control

If the control samples of normal and abnormal levels are within the control limit, and both samples either recover high or both recover low, confirm the calibration system to determine systematic errors.

If an abnormal control recovers low, you can suspect a reagent problem. The twin plot control technique offers the advantage of classification of a systematic error or a random error.

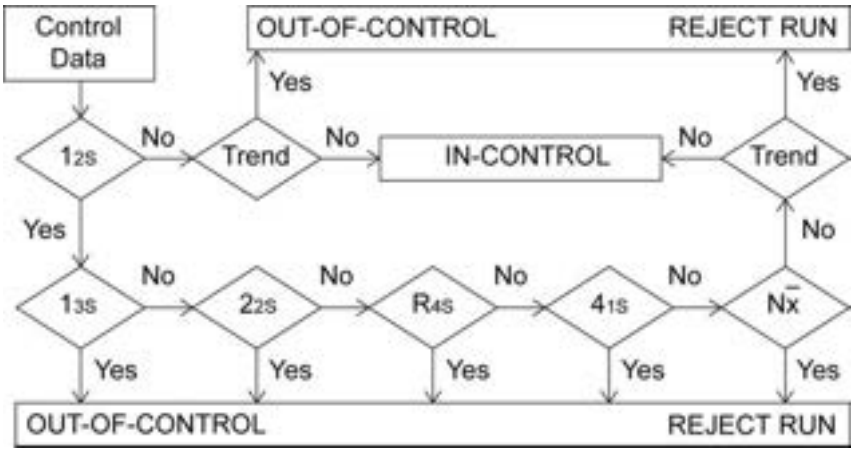
Multi-Rule Control

In the day-to-day control, you check a control error by examining the control chart, but it is difficult to do confirmation of numerous tests on a real time basis. The multi-rule control technique makes it possible to speedily cope with an error realtime, as this control method identifies the rule out of range based on a specific flag.

When employing this control technique, it is necessary to prepare a normal and abnormal level control.

For details of the multi-rule control, refer to the figure shown below.

Figure 1.14 Standard of judgement based on the multi-rule Shewhart technique. (Logic Diagram Applicable to Control Rules)



Symbols for Multi-rule Control and Logic

The following describes the symbols for the multi-rule control and the logic:

- 1_{2S} indicates that five judgment levels given in the accompanying table on the next page are sequentially checked to see whether or not there is any violation of the applicable rule if one piece of control is exceeding the control limit determined as 'MEAN ±2 SD'.
- 1_{3S} is a judgment level for determining if one piece of control has exceeded the control limit determined as 'MEAN ±3 SD'. If these are not beyond the control limit, an inquiry is made to 2_{2S} for the next judgement level. If the control is exceeded, it is judged that quality control has not been properly attained.
- 2_{2S} is a criteria level for judging whether or not the two continuous pieces of control data have exceeded the control limit determined as 'MEAN ±2 SD' in one direction. If these are not beyond the control limit, an inquiry is made to R_{4S} for the next judgment level. If the control is exceeded, it is judged that quality control has not been properly attained. If these are not beyond the control limit, an inquiry is made to 2_{2S} for the

next judgement level. If the control is exceeded, it is judged that quality control has not been properly attained.

NOTE

The term “continuous” above can have the following meanings:

— To be continuous in both directions for one identical control substance.
— To have continuity of high-concentration and low-concentration between control substances.

- R_{4S} is a judgment level for determining whether either of two continuous pieces of data with high and low concentrations has exceeded the control limit specified as ‘MEAN + 2SD’ and whether the other has exceeded the control limit of ‘MEAN –2SD’. In other words, it judges whether the two continuous pieces of data have exceeded 4SD in the same range. If the data is within the control limit, judgment is advanced to the next judgment level, 4_{1S}. If the data is out of the control limit, quality control has not been properly attained.
- 4_{1S} is a judgment level for determining whether or not four continuous pieces of control data have exceeded the control limit of either ‘MEAN +1 SD’ or ‘MEAN -1 SD’. If they have not exceeded either control limit, an inquiry is made to the next judgment standard Nx for necessary judgment, but if they have exceeded the limit, quality control has not been properly attained.
- N_x is a judgment level for determining whether or not continuous N (7 to 10) pieces of control data are above or below the control mean. If the controls have not exceeded the control limit, quality control has been properly attained. If the controls have exceeded the limit, quality control has not been properly attained. The Nx rule uses a maximum of 10 pieces of previous data for judgment.
- Trend evaluates if 4 to 10 sequential results of measurement of the same control material are increasing or decreasing.

If an error is generated by exceeding one of the six multi-rule controls, a flag is attached to the control data. The flags and causes are described below.

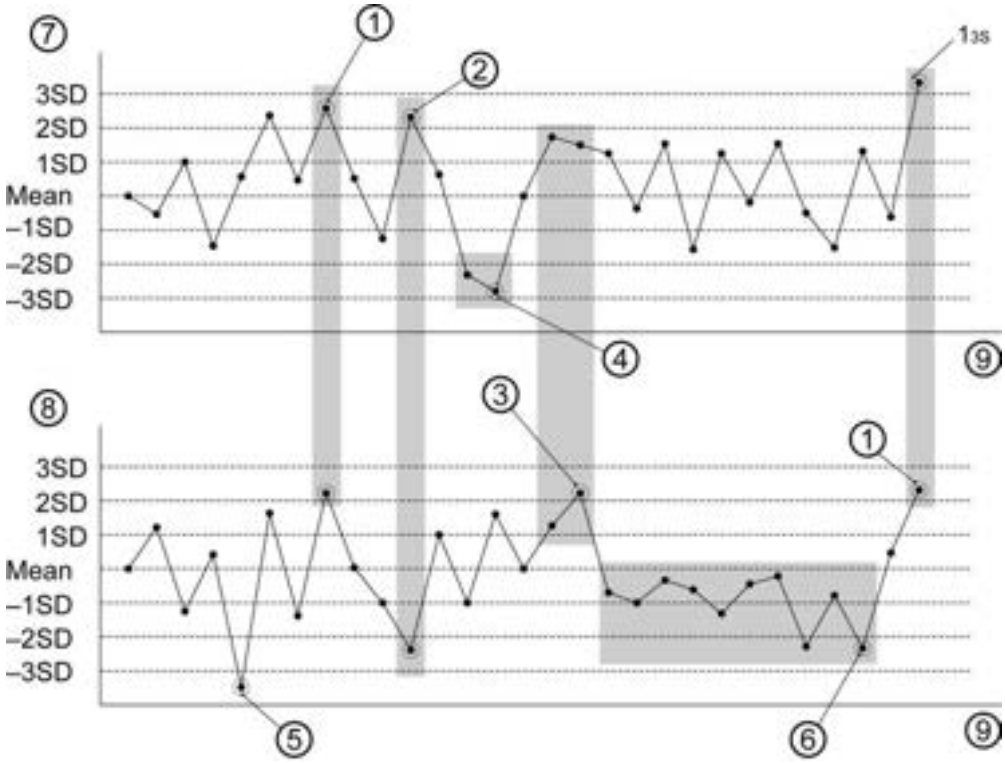
Table 1.8 Multi-rule Control Limit, Flag, and Cause of Error

Control Limit	Flag	Cause of Error
Exceeds 1_{3S}	2Q	Random error
Exceeds 2_{2S}	3Q	Systematic error
Exceeds R_{4S}	4Q	Random error
Exceeds 4_{1S}	5Q	Systematic error
Exceeds Nx	6Q	Systematic error
Trend abnormality	7Q	Increase or decrease in continuous quality control data

Control Errors Example

The following shows an example of control errors according to the multi-rule control:

Figure 1.15 Control Errors Example



1. 2_{2S}: Systemic error. The high and low value controls both exceeded the 2 SD level in one direction. A 3Q flag is generated.
2. R_{4S}: Random error. The high value control exceeded the 2 SD level and the low value control exceeded the -2 SD level. A 4Q flag is generated.
3. 4_{1S}: Systemic error. Four continuous QC results exceeded the 1 SD level in one direction. A 5Q flag is generated.
4. 2_{2S}: Systemic error. The high value control had two continuous results over 2 SD or under -2 SD in one direction. A 3Q flag is generated.
5. 1_{3S}: Random error. One result is either over 3 SD or under -3 SD. A 2Q flag is generated.
6. Nx: Systemic error. Ten continuous results are below the mean. A 6Q flag is generated.
7. High value control
8. Low value control
9. Day

The following describes the possible errors and causes for the random errors and systematic errors shown in the figure above. To troubleshoot the errors, refer to the following:

These are the random errors:

- Dispense accuracy error (sample or reagent): Poor syringe (sample, reagent) dispense accuracy due to syringe integrity or improper installation, air introduced into plumbing system, dirty probe, reagent empty, and so forth.
- Poor photometer accuracy: Lamp deterioration.
- Reagent degeneration: Improper reagent storage or contamination.
- Poor quality control sample: Incorrect sample, different lot, and so forth.
- Insufficient cleaning: Mix bar cleaning improper or insufficient.

- Poor mixing: Mix bar component defective, incorrect mix bar used, cuvette wheel defective.

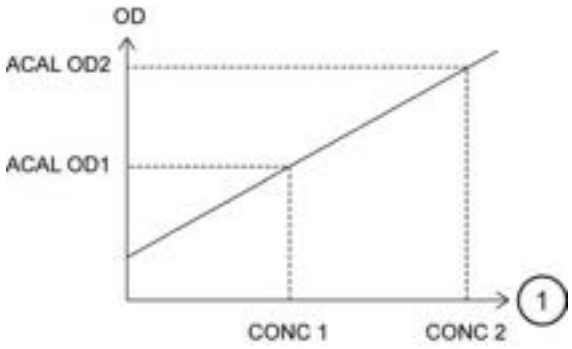
These are the systematic errors:

- Incorrect calibration: Incorrect reconstitution of calibrators.
- Deteriorated reagent: Reagent degeneration, different lot, and so forth.
- Temperature: Improper temperature control.

Summary of Calibration Types

This system allows the operator to generate a maximum of 15 types of calibration curves. The following describes the six major types of calibration curves.

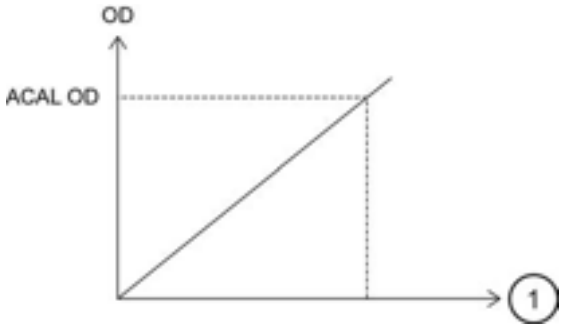
Figure 1.16 ACAL AA



1. CONC: Calibrator Concentration value

- Generate this calibration curve using two different calibrators. The Y intercept is above or below 0 but does not pass through 0 (reagent blank).
- Use this type of calibration curve for fixed point assays.

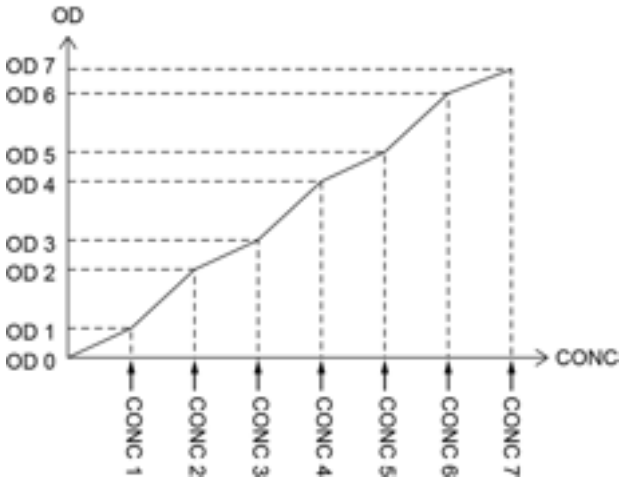
Figure 1.17 ACAL AB



1. CONC: Calibrator Concentration value

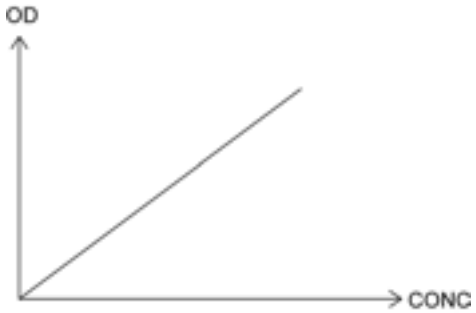
- Generate this calibration curve using a single calibrator and the reagent blank. The Y intercept passes through 0.
- Use this type of calibration curve for end point assays. An example of a test using this type of calibration is Glucose.

Figure 1.18 ACAL 7AB



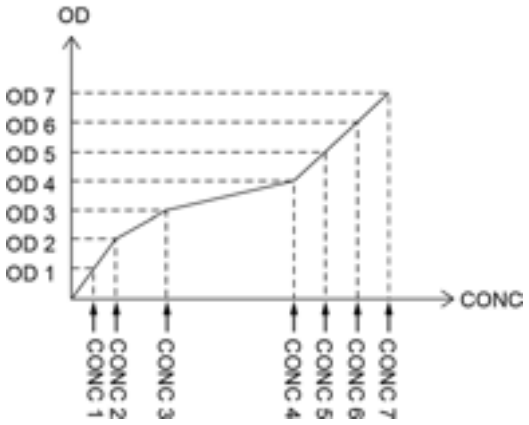
- Generate this calibration curve using a minimum of two calibrators up to a maximum of 7 calibrators. The Y intercept passes through 0.
- Use this type of calibration curve for immunoturbidimetric assays. An example of a test using this type of calibration is C-Reactive Protein.

Figure 1.19 MCAL MB



- Set the calibration coefficient with a theoretical or traceable reference method.
- MB factor derived from extinction coefficient or IFCC reference labs that is a derived factor.
- An example of a test using the Lactate Dehydrogenase calibration.

Figure 1.20 MCAL 7MB



- Generate this calibration curve by entering the OD and concentration for a maximum of 7 calibrators.
- Use this type of calibration curve for immunoturbidimetric tests with constantly curving characteristics.

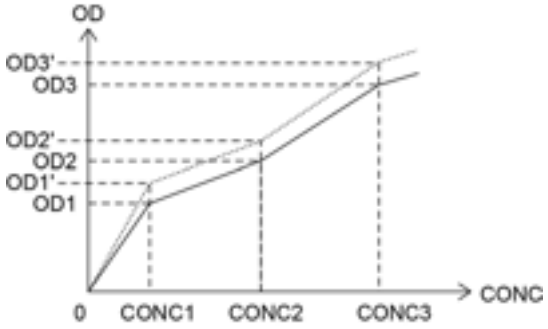
ACAL nAB (single-point correction)

First, analyze one of multiple standard solutions for 2AB to 7AB. By using the ratio between the reaction OD values of this standard solution and the previously measured standard solution, correct the reaction OD values of other standard solutions, and then recreate the calibration chart.

It is possible to correct the calibration chart with two points of OD0 and another OD value, if the standard solution with a concentration of 0 is available.

Example 1: If none of multiple standard solutions has a concentration of 0.

Figure 1.21 Single-point Correction without a Standard Solution Concentration of Zero



A single point update to the calibration curve can be performed for calibrations defined as 2AB to 7AB. A single calibrator is used to obtain a new reaction OD. The ratio between the previously obtained OD and the current OD causes the OD of the other calibrators to be adjusted, and the new calibration curve is calculated.

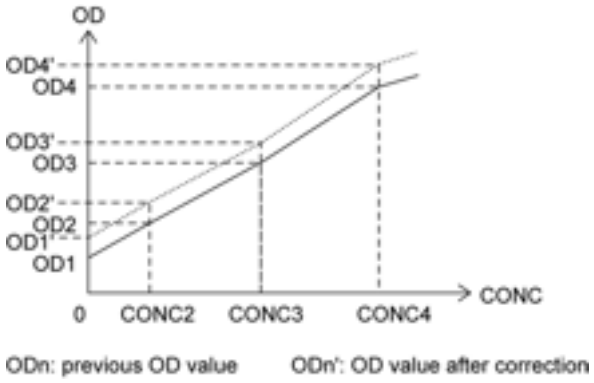
1. Perform the single-point correction.

$$ODn' = ODn \times \frac{OD2'}{OD2}$$

2. Recalculate for the calibration curve.

Example 2: If any standard solution has a concentration of 0.

Figure 1.22 Single-point Correction with a Standard Solution Concentration of Zero



If correction is performed with two points of CONC1 and another (CONC3), execute the following calculation.

1. Use the reaction OD values of CONC1 and CONC3 (OD1' and OD3') as they are.
2. Correct each point as follows.

$$ODn' = \alpha \times (ODn - OD1) + \beta$$

$$\alpha = \frac{OD3' - OD1'}{OD3 - OD1}$$

$$\beta = OD1'$$

Principle of the ISE Measuring Method

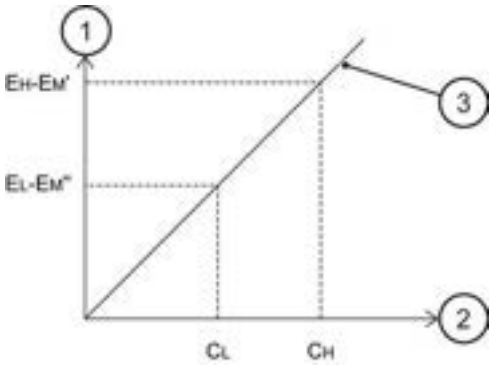
Sample and ISE Buffer Solution are mixed using a specified sample ratio in the sample pot of the ISE module (optional). The mixture is aspirated and passed to the Na, K, and Cl electrodes. The potential generated at the electrodes is measured. ISE MID Standard Solution is cycled between samples to measure the reference potential and to prevent carry-over.

Calibration processing on the ISE

During calibration of the ISE, both ISE MID Standard Solution and Standard Solution H and L, which have a known concentration, are measured. The relationship between the electrode potential and ion concentration at that time is obtained, and Na, K, and Cl calibration setup coefficient S (slope) is calculated.

Calibration

Figure 1.23 Calculation of Slope



1. Potential difference (mV)
2. CONC (logarithm) mmol/L
3. Calibration

C_H	A known concentration of Standard Solution H used for calibration
C_L	A known concentration of Standard Solution L used for calibration
E_H-E_M'	A potential difference between Standard Solution H and ISE MID Standard Solution
E_L-E_M"	A potential difference between Standard Solution L and ISE MID Standard Solution

The system creates a calibration using a potential difference between the two points of known concentration.

Correction by M-CAL

M-CAL at the ISE is data correction using a calculation formula, Y = AX + B.

Y: corrected value, X: actual measurement.

Coefficients A and B are obtained in the following way.

Correlation regression with a measurement (y) obtained from the system before correction and value (x) obtained from any conventional method or standard method.

Coefficients A and B can be obtained by a 3-point regression calibration or Manual calculation.

y = ax + b

gives

x= (1/a)y - (b/a)

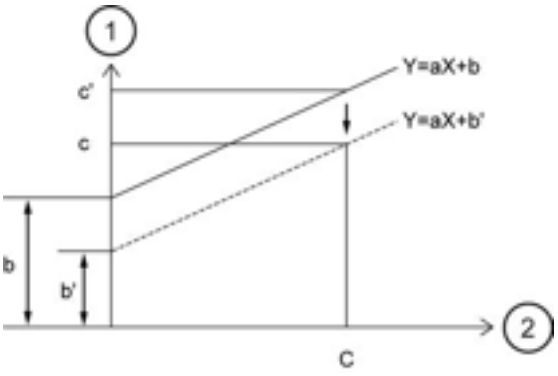
Therefore, A =-1/a, B = -b/a

There are two methods to perform M-CAL:

- Manual: Obtain A and B with the above listed equations and enter them as the factors.
- CRS (3-point regression CAL): Used only in Japan.

Correction by A-CAL

Figure 1.24 Correction by A-CAL



1. Y (measured value)
2. X (known concentration of a sample subject to A-CAL)

- Corrected value: c' - c
- b'=b-(c'-c)

  a = factor

  b = offset

Let a known concentration of a sample for A-CAL be c, and let the measurement obtained by this system from a sample for A-CAL after an M-CAL correction be c´. In order to make the known concentration of the sample for A-CAL and a measurement obtained by this system consistent, correct the difference between c and c´ using A-CAL. In this case Y = aX + b is Y = aX + b´.

This A-CAL correction can be applied to values that have been subject to an M-CAL correction.

Principle of the Realtime Water Blank Check

The realtime water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the deviation in the water blank reading on a cuvette exceeds a tolerance level, a `Photometry Error During Cuvette Wash` alarm is generated.

A `Photometry Error During Cuvette Wash` alarm is generated when a cuvette overflow is detected, and when unstable photometry is detected. Unstable photometry can be caused by:

- Improperly placed cuvettes in the cuvette wheel
- Dirty cuvettes
- Insufficient amount of wash solution being supplied to clean the cuvettes
- A deteriorating lamp

When a `Photometry Error During Cuvette Wash` alarm is generated, check to see if a cuvette overflow has occurred. Refer to the AU680 Instructions for Use.

- If a cuvette overflow occurs, refer to the AU680 Instructions for Use. It is necessary to identify and re-analyze all samples affected by the cuvette overflow.
- If a cuvette overflow did not occur, the `Photometry Error During Cuvette Wash` alarm was generated by unstable photometry. Refer to the AU680 Instructions for Use to determine the cause of the error and perform corrective actions.

Key Sub-Processes

This section describes some important analysis steps.

Sample Identification

A test order (requisition) is an instruction to perform specified tests on a sample. When a sample is placed onto the system, the test order (requisition) information is used to link the sample to the required tests. The system must be able to identify samples correctly. Basic information on the sample is coded in the rack bar code. This bar code is used to identify the sample type (for example, serum, urine, others) loaded on the rack. The system can also use sample bar codes to link test order (requisition) information to each sample to be tested.

There are three analysis modes for recognizing samples on racks.

Barcode (Sample ID) Analysis Mode

The system reads the sample bar code on each sample cup and then links this information to a corresponding order (requisition) to perform analysis. Samples can be in any order, and empty spaces are allowed on the racks. It is critical to test results that sample bar codes match sample orders (requisitions).

Sequential Analysis Mode

The system analyzes the first sample on the first rack presented, using the information in the first test order (requisition). It uses the second test order (requisition) for the second sample on the rack, and so on. The sample bar code label is not read in sequential mode. There is a Sequential Sample ID Read option to have the system read a sample bar code label in sequential mode. Refer to Analysis Mode Screen for more information.

Samples should be placed on the racks in numerical order, without empty spaces on the rack.

WARNING

Running the system in sequential mode (that is without reading sample bar code label) is not recommended because of the possibility of sample and result mismatch. If a sample must be run without a sample bar code label, be careful and have extra cross checks in place.

To ensure correct sample analysis in sequential mode, confirm that there are no empty spaces in the racks. Never mix different sample types on one rack.

NOTE

When the AU680 is connected to a laboratory automation system, the only option for programming sequential mode is the STAT table.

Rack No. Analysis Mode

The system reads the rack ID and assigns the sample No. according to the cup position in the rack. The samples must be set in the rack in the order entered for the samples at the time of sample order (requisition). Sample bar codes are not read in Rack No. analysis mode.

For example, when the samples from No. 1 to No. 10 are set on rack ID 0001 and the samples from No. 11 to No. 20 are set on rack ID 0002, sample No. 14 can be found in position 4 on rack ID 0002 and sample No. 57 can be found in position 7 on rack ID 0006. In Rack No. analysis mode, the racks can be placed onto the feeder in any order. The maximum rack ID for Rack No. analysis mode is up to 999.

WARNING

In Rack No. analysis mode, use extreme caution when placing the samples in the racks to avoid concordance errors (incorrect sample and result). Take time to perform crosschecks on racks and samples.

NOTE

When the AU680 is connected to a laboratory automation system, Rack No. analysis mode cannot be programmed.

Sample Transfer

Sample tubes or cups containing sample are placed on the system using sample racks or placed on the STAT table. When **Start** has been selected, the system moves racks to the sample probe. Samples are started from the STAT table by selecting **STAT Start (F1)** from **Home > STAT Status**. The system determines the test order (requisition) information and the sample is aspirated by the sample probe.

The sample volume and diluent volume for each test are programmed in **Specific Test Parameters**.

After dispensing, the sample probe is washed in the wash well with deionized water internally and externally.

Reagent Transfer

The system has two reagent transfer probes. Any required reagent is aspirated from the corresponding reagent bottle in the reagent refrigerator and dispensed into the cuvette in the incubation bath. The system uses information programmed in **Specific Test Parameters**

to determine the quantity of reagent to use. A mixture of sample and reagent which has been dispensed into one cuvette is called reaction fluid.

The reagent probes are washed internally and externally with deionized water, between each reagent dispense, to ensure there is minimal reagent carryover. In addition, contamination avoidance parameters can be programmed. For more information, refer to Contamination Parameters Screen.

Reaction Fluid Mixing

The mix bar component uses fluororesin-coated mix bars to mix the reaction fluid in the cuvette to a uniform mixture. Two mix bar components are provided. Each of the two mix bar components has three sets of mix bars, which are used as follows: while one of three sets is engaged in mixing, the other two are washed in the wash well with diluted wash solution and rinsed with deionized water.

Reaction Fluid Incubation and Washing

The cuvette wheel is set in an incubation bath to keep the reaction temperature in the cuvette at a constant level.

When the photometer readings are complete, the reaction fluid in a cuvette is aspirated by the wash nozzle component, and the cuvette is washed with diluted wash solution, rinsed with deionized water, and then dried.

Photometric Measurement

Various chemical components in the sample and the reagents have a color reaction in the cuvette. Light from a halogen lamp is passed through the reaction fluid, and is separated into specific wavelengths by a diffraction grating. A photodetector measures the optical density of reaction fluid. Measurement is performed at 18-second intervals throughout the reaction period. The measured values for the reaction period and wavelengths defined in the specific test parameters are used for concentration calculation.

Online Analysis and Analysis Using Keyboard Entries

Real-time online

Realtime online analysis is possible when **System > Online > Setup Test Requisition Information Receive** is programmed to Realtime, and the AU680 is interfaced to a laboratory information system. In responding to any inquiry from the analyzer to the laboratory information system, everything is automatically processed.

If a laboratory information system and the AU680 are connected real-time online, the operator does not have to perform test orders (requisitions) from the AU680 computer.

Batch online

Batch online analysis is possible when **System > Online > Setup Test Requisition Information Receive** is programmed to Batch, and the AU680 is interfaced to a laboratory information

system. The sample information (such as test item, and so on) of multiple samples is batch-inquired to the laboratory information system through the operation at the AU680.

Keyboard entry

Manual sample ordering (requisition) is performed by sample number or sample ID number at the AU680 computer.

Manual sample ordering (requisition) at the AU680 computer can be performed with or without a laboratory information system.

Sample Identification and Date and Time

Sample No.

This is a 4-digit number used to identify each sample. Sample number calculation method varies for each analysis mode.

For more information on Sample ID and Rack ID, refer to Sample Identification.

Sample ID

A sample ID used to identify each sample.

In the sample ID (barcode) analysis, the bar code label attached to each sample cup is read and handled as the sample ID.

Rack ID

A rack ID is used for identifying each rack. In rack No. analysis, the sample No. of each sample is automatically assigned using the rack ID. When the AU680 is connected to a laboratory automation system, racks are not used on the system.

System date and time

This is the system date and time under the management of the internal clock of the system.

Index date and time

An index, created by setting the date and time, is a data file used as the main search key for sample data.

The current date and time is automatically set as the index date and time on starting up the system; however, this is a user-defined option.

Understanding and Handling Reagents, Calibrators, and Controls

This section describes the reagents used on the AU680.

Reagents

Beckman Coulter reagents are highly concentrated, and most reagents are ready to use.

The system can use reagents, calibrators, and QC samples supplied by manufacturers other than Beckman Coulter. Confirm usability with the reagent manufacturer or distributor.

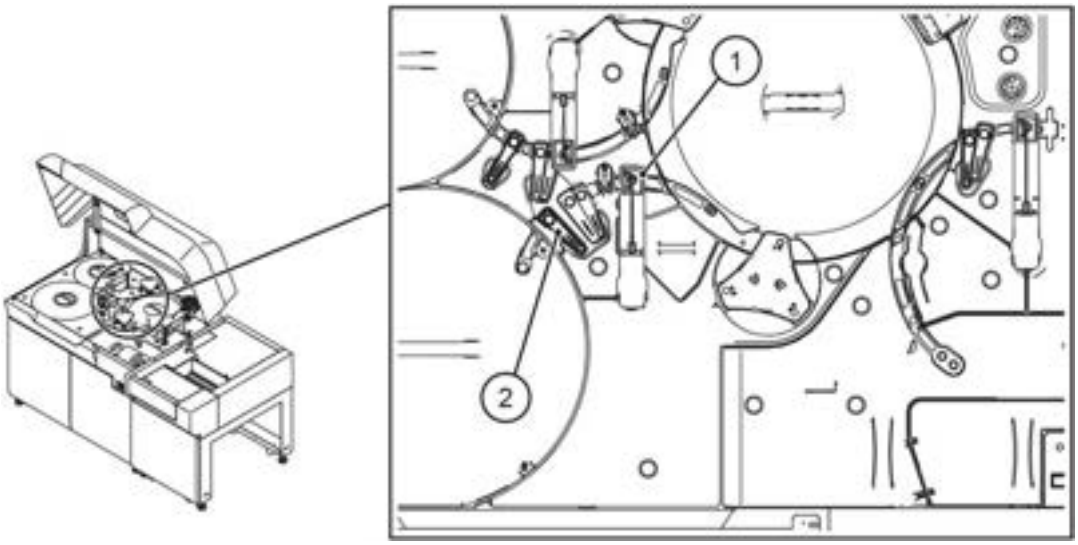
Reagents are supplied in bottles of 15 mL, 30 mL, 60 mL, or 120 mL. Reagent bottles containing reagents are set in the reagent refrigerator fixed by adapters and partitions, depending on the size.

The bar code label on a reagent bottle is read and registered with the system.

Sample Diluent

For samples with a high concentration, deionized water or other diluent can be used for automatic dilution analysis. The diluent is in a 60 mL bottle placed in a designated diluent bottle position labeled 61. Diluent/W2 near the reagent (R1) refrigerator.

Figure 1.25 Sample Diluent Bottle Position



1. Reagent probe
2. Sample diluent bottle

Calibrator

A maximum of 200 different calibrators can be programmed on the system.

Calibration should be performed in the following situations:

- When a reagent bottle has changed, and the Calibration Specific screen has been programmed to calibrate new bottles.
- When a reagent lot has changed.
- When the same lot has been used on the system for a predefined number of days.
- QC recovery is outside specified limits.
- There has been major preventive maintenance, or critical part replacement, and QC performance is affected.

For more information on test specific calibration, refer to the Reagent Instructions for Use.

For more information on operation precautions, refer to the AU680 Instructions for Use.

Quality Control Sample

Quality Control (QC) analysis should be performed after calibration and some maintenance procedures to confirm that the system is working correctly. QC analysis should also be performed at regular intervals for verification of system stability. Perform this check using a QC sample from the QC supplier.

For more information on operation precautions, refer to the AU680 Instructions for Use.

ISE Quality Control Material

Commercial Control Material for the ISE

Beckman Coulter advises using the most widely accepted, reliable ISE control material available locally. ISE tests can be affected by substances in control serum.

Commercial control material contains additives for regulating the density of components, and various preservatives. If this type of control material is measured using an ion selective electrode, the added materials can cause problems with the electrode, and could cause measurement errors including abnormal data.

⚠ CAUTION

The following items affect measurement:

- **Errors can result in samples containing antibiotics or other drugs.**
- **The K and Cl electrodes are not affected by bilirubin, but small positive errors occur in the Na electrode.**
- **Positive errors occur in the Cl electrode caused by halogen ions (Br, I).**
- **A positive error is recognized in the K electrode for samples where the hematocrit value is 65% or more. If a hemolytic sample is used, K shows an excessively positive error.**
- **Use the anticoagulant Lithium Heparin. Any other anticoagulants can cause an error in measured values. Use the anticoagulant immediately after collecting blood.**
- **To prevent fluctuations caused by sample evaporation, serum and plasma samples should be kept tightly closed in a refrigerator. Also, samples stored in a refrigerator should be measured after the temperature of the sample has returned to room temperature.**

CHAPTER 2

Parameters

Common Test Parameters Menu

Test Name Screen

Use this screen to program test parameters including the test name, reagent ID, and reagent short alarm.

Test numbers 1 to 120 are pre-programmed as closed or open test numbers.

- Closed Test Numbers - Beckman Coulter test parameters are available on a validated CD that a Beckman Coulter representative loads during installation. The Beckman Coulter tests are loaded onto closed test numbers. Closed test numbers reduce manual programming time and possible programming errors.
- Open Test Numbers - The system supports the ability to add tests not from Beckman Coulter. Open test numbers are available for reagents not from Beckman Coulter.

A maximum of 120 tests can be programmed. The contents of this screen can be printed.

Table 2.1 Test Number Programming Options and Descriptions

Test Number	Programming Options	Description
1 to 90	Closed or Open	Customer specific
91 to 95	None	FSE Troubleshooting
96 to 99	None	LIH, Na, K, Cl
100 to 102	None	HbA1c
103 to 120	Closed or Open	Customer specific

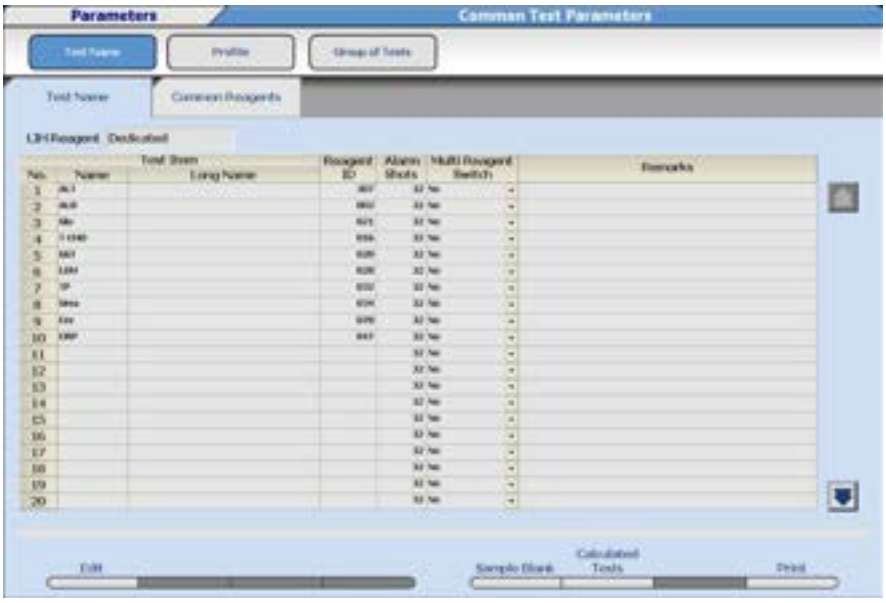
Some fields in **Specific Test Parameters** are not programmable for closed test numbers. For detailed information, refer to General Screen.

All other **Parameters** menus, including **Common Test Parameters** (Test Name, Long Name, Reagent ID, Alarm Shots, and Multi Reagent Switch) are programmable for closed or open test numbers.

Test Name Tab

Select **Menu List > Parameters > Common Test Parameters > Test Name > Test Name**.

Figure 2.1 Test Name Tab



Program the following items as required.

Table 2.2 Test Name Tab Description

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	Dedicated means using test number 96. LIH with LIH Reagent (OSR62166) as the reagent. LIH Reagent has a reagent ID and can be placed in any open position in the R1 refrigerator. Non Dedicated means using an existing (on-board) test and reagent for LIH testing. A maximum of three tests can be programmed to the Group for LIH analysis. To program Dedicated or Non Dedicated, select **Edit (F1)** and then **LIH (F7)**. In LIH Reagent select **Dedicated** or **Non Dedicated**. Select **Close**.
No.	1 to 120	A maximum of 120 tests can be programmed on the system. Closed test numbers are pre-programmed; open test numbers are manually programmed. Tests are processed on a sample in the order (1 to 120) displayed. Tests 91. to 95. FSE Troubleshooting, 96. LIH, 97. Na, 98. K, 99. Cl, 100. HbA1c%, 101. T-Hb, and 102. HbA1c are pre-programmed test numbers that cannot be changed.
Test Name	An abbreviated test name.	A maximum of 6 characters. Test names for test numbers 96 to 102 are pre-programmed in the software and cannot be changed.
Long Name	A complete test name.	A maximum of 20 characters.

Table 2.2 Test Name Tab Description (Continued)

Item	Contents	Input Notes
Reagent ID (for all markets except Japan)	3 digits (000 to 999)	The 3-digit Reagent ID located on the top, right side of the chemistry setting sheet, or the first 3 digits from the reagent ID label. Enter the same reagent ID for two tests to use the same bottle of reagent. Available for reagent ID or fixed reagents. In **Reagent Management**, both test names display for the bottle.
Manufacturer ID (for Japan only)	3 digits (000 to 999)	The first three digits of the reagent ID. Manufacturer ID is defined by the reagent manufacturer. Refer to the reagent Instruction for Use.
Test Code (for Japan Only)	2 digits (00 to 99)	The 2 digits of the reagent ID following the first 3 digits. Refer to the reagent Instruction for Use.
Alarm Shots	1 to 200. The default is 32.	Quantity of tests remaining when a reagent short alarm is generated.
Multi Reagent Switch	Yes or No	Yes: When multiple sets of an R1/R2 are in use, and the R1 or R2 becomes empty in the first set, the analyzer switches to the second set of R1/R2 at the same time. One indicator bar displays for R1 and R2 in **Reagent Management**. No: The default setting is No. If an R1 or R2 becomes empty, the analyzer does not switch to the second set of R1/R2 at the same time. An indicator bar displays for R1 and R2 in **Reagent Management**. **CAUTION** **Beckman Coulter recommends programming Multi Reagent Switch to Yes for all Beckman Coulter reagents.**
Remarks	Displays a comment indicating the test is a sample blank test or a calculated test.	Remarks display automatically and cannot be entered.

CAUTION

Changing the test name affects all results associated with that test number. Any previously reported results (with the old test name) are assigned the new test name. Extreme caution must be applied when making any changes to the test name.

Do not change the test name without noting the time and date the change occurred and then being sure any results printed before this time and date are reviewed and correctly identified.

IMPORTANT

Tests are processed on a sample in the test number order (1 to 120) displayed, with some exceptions. For information on contamination prevention, refer to Contamination Parameters Screen.

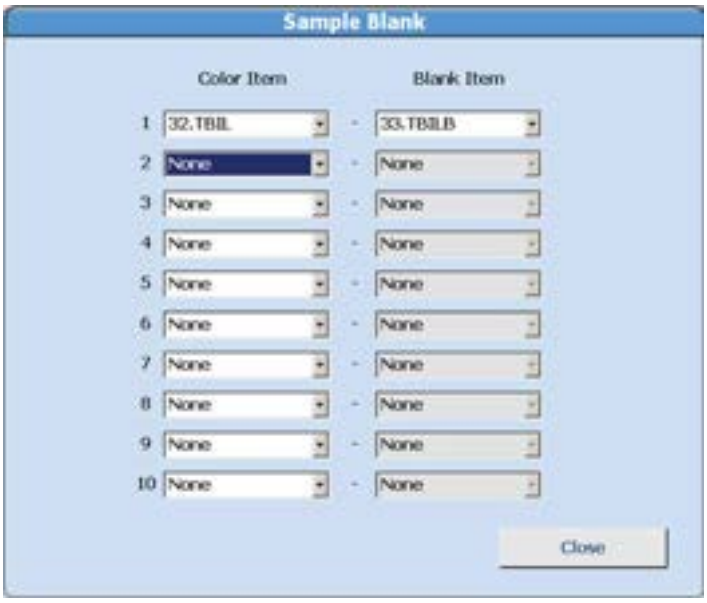
Sample Blank (F5)

Interference from other substances in the serum may affect the optical density measured. To correct this interference, a sample blank correction is performed. Sample blank correction uses the terms color and blank. These identify the active reagent (color) and the inert reagent (blank). The OD value of Y obtained from the formula Y = X - B (X is the OD value of a color item and B is the OD value of a blank item) is multiplied with a factor. A maximum of 10 sample blank tests can be set.

Sample Blank tests are total and direct bilirubin. These tests contain an R1 color reagent and an R1 blank reagent. Program these tests in **Sample Blank (F5)** to perform the sample blank correction.

- Select **Sample Blank (F5)**. The Sample Blank dialog opens.

Figure 2.2 Sample Blank Dialog



- In **Color Item**, select the test to assign a color item.
- In **Blank Item**, select the test to assign a blank item.
- Select **Close** to save the programming.

NOTE

Calculated tests cannot be programmed as Color Items or Blank Items.

Calculated Tests (F6)

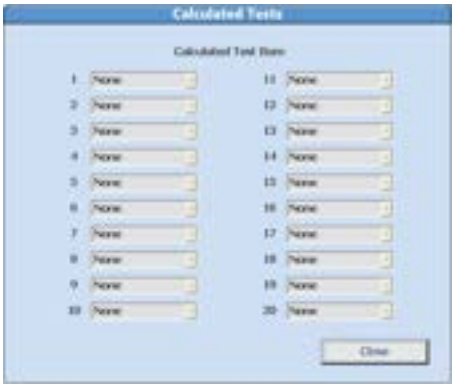
A maximum of 20 tests can be programmed as a calculated test. Refer to Calculated Tests Screen to program the specific tests and formula for the calculation.

NOTE

A calculated test name must be programmed in the Test Name tab before it can be selected in **Calculated Tests (F6)**.

- Select **Calculated Tests (F6)**. The Calculated Tests dialog opens.

Figure 2.3 Calculated Tests Dialog



- Select the calculated test name. Select **Close** to save the programming.

Common Reagents Tab

Common Reagents can be programmed for the R1-2 of a 3-part reagent that can be used for more than one test. The common reagent is assigned to the test in **Specific Test Parameters**. A maximum of 10 common reagents can be set.

Select **Menu List > Parameters > Common Test Parameters > Test Name > Common Reagents**.

Figure 2.4 Common Reagents Tab

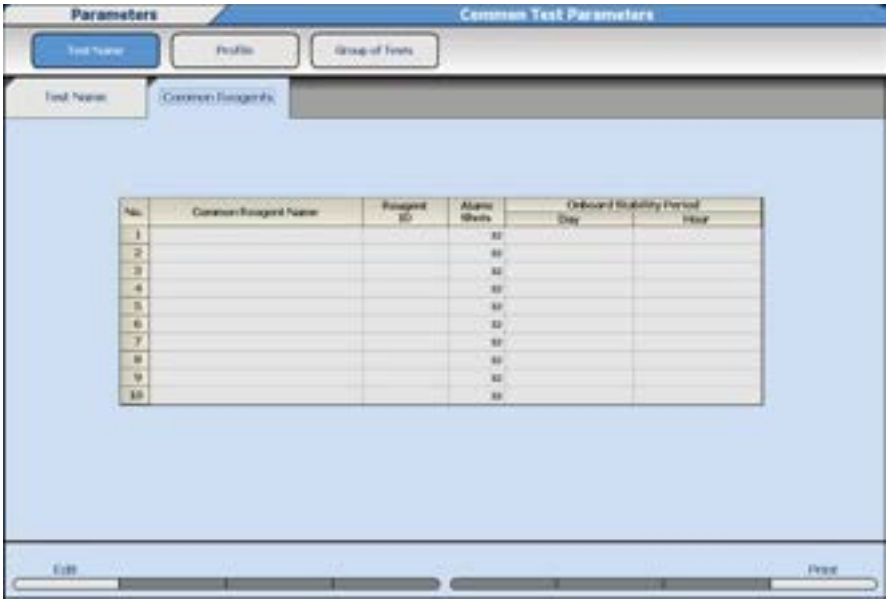


Table 2.3 Common Reagents Tab Description

Item	Contents	Input Notes
Common Reagent Name	Reagent name	A maximum of 6 characters
Reagent ID	3 digits (000 to 999)	The 3-digit Reagent ID located on the top, right side of the chemistry setting sheet, or the first 3 digits from the reagent ID label.
Alarm Shots	1 to 200. The default is 32.	Quantity of tests remaining when a reagent short alarm is generated.
Onboard Stability Period	Day (0 to 999) Hour (0 to 23)	

Profile Screen

A profile is a group of tests that are typically ordered (requisitioned) at the same time. Using a profile reduces the quantity of selections needed, as a single profile is selected instead of multiple tests. A maximum of 100 profiles (Number 0 to Number 99) can be programmed for samples, reagent blank, calibration, and QC. A maximum of 99 tests can be programmed in a profile. The quantity of sample blank tests, LIH, and sample type limits the quantity of tests that can be programmed in a profile.

Each profile is assigned a profile name.

You cannot select unavailable tests.

You can only select ISE tests when the sample type is Serum or Urine.

For more information, contact Beckman Coulter.

Sample Tab

Profile 0 is the Default profile in the Sample tab. Profile 0 is automatically performed in the following situations:

- A bar code label read error occurs.
- No order (requisition) found for a sample.
- Online errors.

Select **Menu List > Parameters > Common Test Parameters > Profile > Sample**.

Figure 2.5 Profile: Sample Tab

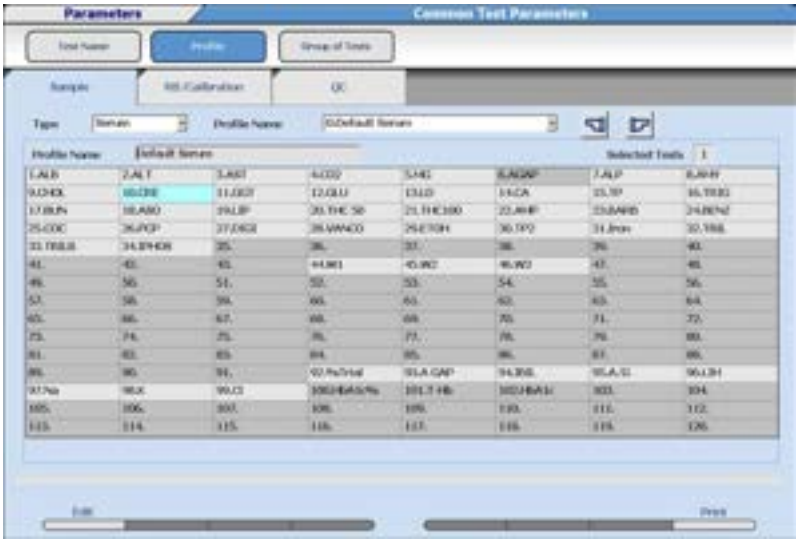


Table 2.4 Sample Tab Description

Item	Contents	Input Notes
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Profile Name (option)	0 to 99	Profile 0 is the default profile.
Profile Name (selected option)	Profile name	A maximum of 20 characters.
Selected Tests	Displays the quantity of tests selected (highlighted in blue) in the Profile.	

NOTE

Tests that are grayed out cannot be selected.

ISE tests can be selected only when the sample type is Serum or Urine.

RB/Calibration Tab

Select **Menu List > Parameters > Common Test Parameters > Profile > RB/Calibration**.

Figure 2.6 Profile: RB/Calibration Tab

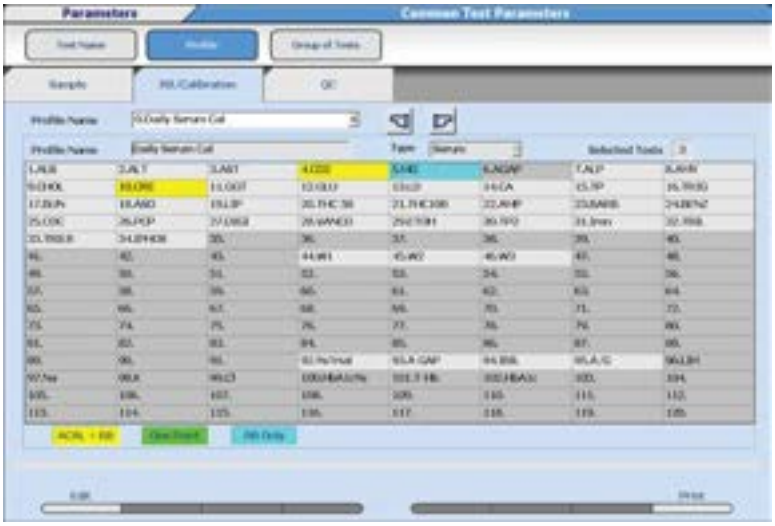


Table 2.5 RB/Calibration Tab Description

Item	Contents	Input Notes
Profile Name (option)	0 to 99	
Profile Name (selected option)	Profile name.	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the quantity of tests selected (highlighted in yellow, green, or blue) in the Profile.	Select **Edit (F1)**, and then select **Calibration Option (F5)** to change between the available calibration options: ACAL + RB (yellow) One Point (green) RB Only (blue) Refer to Summary of Calibration Types and Calibration Specific Screen for more information.

NOTE

The programming in **Calibration Specific** determines the calibration options available in **Calibration Option (F5)**.

Tests that are grayed out cannot be selected.

ISE tests can be selected when the ISE calibration type is ACAL.

QC Tab

Select **Menu List > Parameters > Common Test Parameters > Profile > QC**.

Figure 2.7 Profile: QC Tab

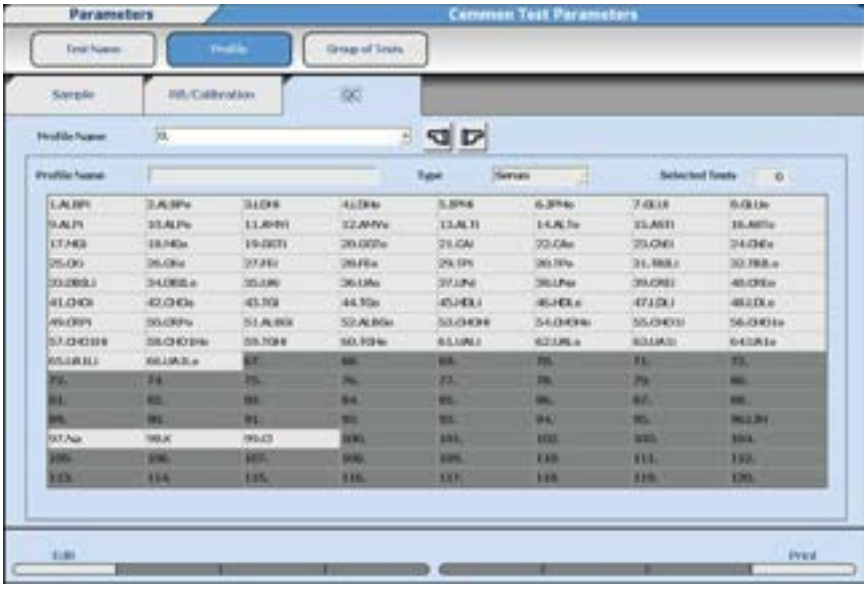


Table 2.6 QC Tab Description

Item	Contents	Input Notes
Profile Name (option)	0 to 99	Profile numbers 87 to 99 are default QC profiles determined by Group and Type. Refer to the Note below.
Profile Name (selected option)	Profile name.	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the quantity of tests selected (highlighted in blue) in the Profile.	

NOTE

Tests that are grayed out cannot be selected.

NOTE

QC profiles 87 to 99 are the default QC profiles that are automatically ordered (requisitioned) in **Home > Rack Requisition Sample > QC**. The QC profile numbers 87 to 99 correspond to a specific Group and sample type:

- Number 87: Serum: For Group 1
- Number 88: Serum: For Group 2
- Number 89: Serum: For Group 3
- Number 90: Urine: For Group 1
- Number 91: Urine: For Group 2

- Number 92: Urine: For Group 3
- Number 93: Other-1: For Group 1
- Number 94: Other-1: For Group 2
- Number 95: Other-1: For Group 3
- Number 96: Other-2: For Group 1
- Number 97: Other-2: For Group 2
- Number 98: Other-2: For Group 3
- Number 99: Whole Blood: For Groups 1, 2, and 3

Group of Tests Screen

A Group is a programmed group of tests that can be set as the tests on-board the analyzer. Three Groups of tests can be programmed. The Group is specified in **Start Condition**, and the system confirms the reagents required for the Group are in the reagent refrigerators during the reagent check.

A maximum of 60 photometric tests plus the 3 ISE tests (63 total) can be programmed in each Group.

Tests print in the order tests are assigned to the Group. To change the test print order, select **Menu List > Parameters > Common Test Parameters > Group of Tests** and then select **Edit (F1)**. Select the test to move, then select **Forward (F2)** or **Backward (F3)**. LIH and calculated tests print last.

Select **Menu List > Parameters > Common Test Parameters > Group of Tests**.

Figure 2.8 Common Test Parameters: Group of Tests Screen

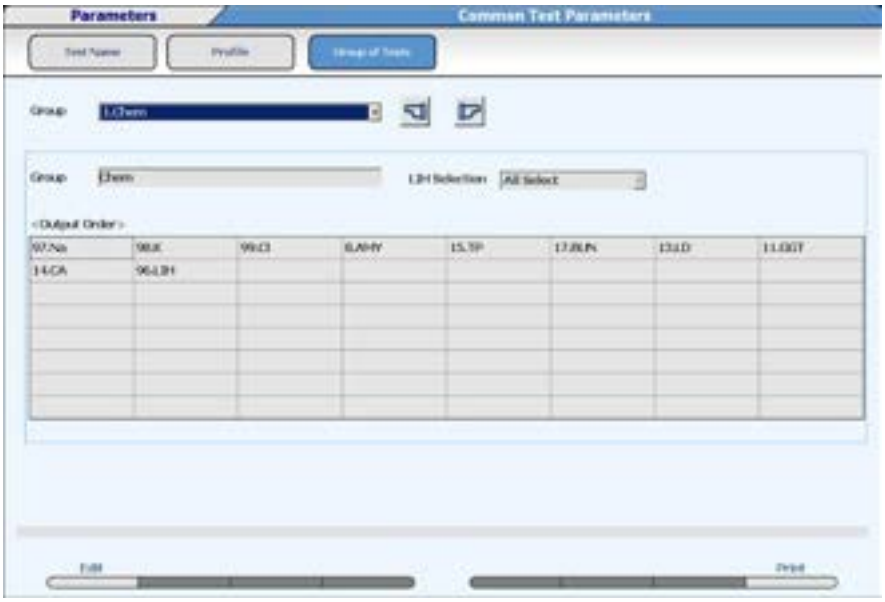


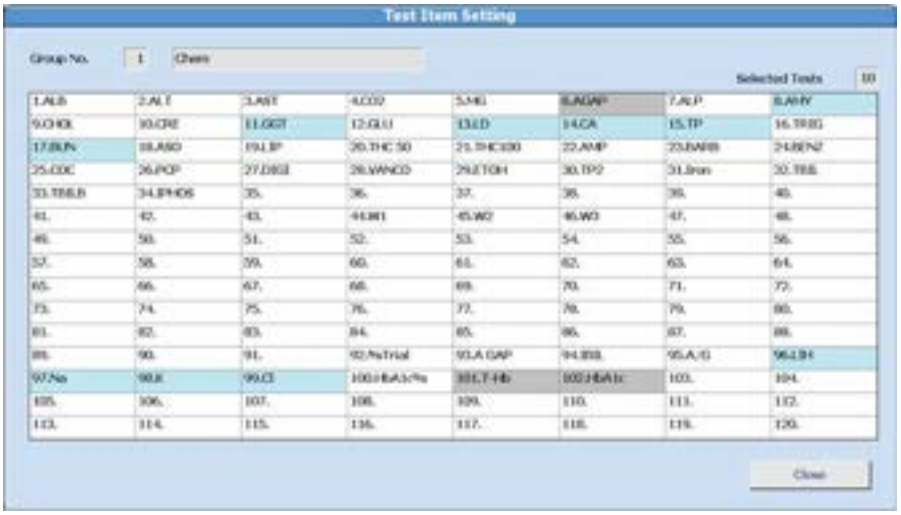
Table 2.7 Group of Tests Screen Description

Item	Contents	Input Notes
Group (option)	1, 2, or 3	

Table 2.7 Group of Tests Screen Description (Continued)

Item	Contents	Input Notes
Group (selected option)	Group Name	A maximum of 20 characters.
LIH Selection	All Select or Selectable	All Select means LIH is automatically ordered (requisitioned) on every sample. Selectable means LIH is ordered (requisitioned) as needed on samples. If All Select is programmed, test 96. LIH must be added to any Group (1, 2, or 3) that has tests programmed, or a red Incorrect Parameter message appears, and analysis cannot be started.
LIH Test Item Setting (F6)	A maximum of 3 tests for LIH analysis.	This option is only available if LIH Reagent is set to **Non Dedicated** in **Menu List > Parameters > Common Test Parameters > Test Name**. Non Dedicated means using an existing (on-board) test and reagent for LIH testing. A maximum of 3 tests from the Group can be selected for LIH analysis.
Test Item Setting (F5)	Select (highlight in blue) the tests to include in the Group.	Select tests in the order to display and print. The <Output Order> displays the order the tests print. Calculated tests are inaccessible (gray) to select (highlight in blue) to include in the Group because calculated tests are performed automatically when all tests that are part of the calculated test are ordered (requisitioned) on a sample.
Forward (F2) and Backward (F3)	Change the display and print order (<Output Order>) of the tests.	Select **Edit (F1)**, then select the test to move, then select **Forward (F2)** and **Backward (F3)**. LIH and calculated tests print last.

Figure 2.9 Test Item Setting Dialog



Specific Test Parameters Menu

Program specific test parameters, LIH parameters, ISE parameters, HbA1c parameters, calculated tests, and reference ranges for tests.

CAUTION

Incorrect specific test parameters cause errors in analysis results, and can cause an incorrect diagnosis. Specific test parameter settings should be visually confirmed against published settings, and by analysis using materials with known concentrations.

For more information on displaying a list of programmed values, refer to Table 2.16 General Screen Description.

General Screen

Program the specific analysis parameters for each test. Program the test name before programming specific tests parameters. For more information, refer to Test Name Screen.

Test numbers 1 to 90 and 103 to 120 have been pre-programmed as closed or open to meet your laboratory's specific requirements.

The only difference in programming a closed or open test number is the programmable parameters in **Specific Test Parameters**.

- Closed test numbers have fixed parameters (not programmable) and programmable parameters. After selecting **Edit (F1)**, the background color is gray for fixed parameters and white for programmable parameters.

  — Fixed Parameters (Not Editable)

  - Sample Volume and Dilution
  - Reagent Volume R1 (R1-1) and Dilution
  - Reagent Volume R1-2 and Dilution
  - Reagent Volume R2 (R2-1) and Dilution
  - Wavelength (Primary and Secondary)
  - Method
  - Measuring Point-1 (First and Last)
  - Measuring Point-2 (First and Last)
- Editable Parameters
  - Pre-Dilution Rate and Diluent Bottle
  - Reaction Slope
  - Reagent OD Limit First (Low and High)
  - Reagent OD Limit Last (Low and High)
  - Dynamic Range
  - Correlation Factor
  - Onboard Stability Period

- All parameters are programmable for open test numbers.
- All other **Parameters** menus, including **Common Test Parameters** (Test Name, Long Name, Reagent ID, Alarm Shots, and Multi Reagent Switch) are programmable for closed or open test numbers.

⚠ CAUTION

When Saving or Loading Parameters:

Follow all cautions in the AU680 Instructions for Use when using external media to save or load parameters. One CD-R or USB flash drive is required for the purpose of saving parameters for each AU680.

The configuration of test numbers from 1 to 90 and 103 to 120 pre-programmed as closed or open can vary on each AU680 to meet specific laboratory requirements. The test number configuration for closed or open is saved with parameters on the external media. If the parameters from one AU680 are loaded onto another AU680 with a different configuration of closed and open test numbers, the following message displays after 30 days when the AU680 is turned On. If the following System Start message displays, contact Beckman Coulter.

Figure 2.10

Select **Menu List > Parameters > Specific Test Parameters > General**.

Figure 2.11 Specific Test Parameters: General Screen

Enter specific test parameters from the chemistry setting sheet. If a field is grayed out, it is not programmable.

Table 2.8 General Screen Description

Item	Contents	Input Notes
Test Name	Abbreviated test name selected from drop-down.	The abbreviated test name is programmed in **Common Test Parameters > Test Name**.
Type	Serum, Urine, Other-1, or Other-2	
Operation	Yes or No	Yes: the test is operational for the Type displayed. No: the test is not operational for the Type displayed. If a test is programmed to No, it is not available to order (requisition) or run. The test displays gray and is inaccessible in the list of tests.
Sample Volume and Dilution (for all markets except Japan)	If Dilution is 0 µL, then Sample Volume can be set from 1.6 µL to 25.0 µL. If Dilution is 10 µL, then Sample Volume can be set from 1.6 µL to 20.0 µL. Minimum Sample Volume is 1.6 µL.	Sample Volume can be set in increments of 0.1 µL. Dilution is Deionized (DI) water (0 or 10 µL) dispensed for a sample dilution following the sample dispense. If Dilution is set to 0 µL, then an extra 5 µL of sample is aspirated for dispensing accuracy.

Table 2.8 General Screen Description (Continued)

Item	Contents	Input Notes
Sample Volume and Dilution (Japan only)	If Dilution is 0 µL, then Sample Volume can be set from 1.0 µL to 25.0 µL. If Dilution is 10 µL, then Sample Volume can be set from 1.0 µL to 20.0 µL. Minimum Sample Volume is 1.0 µL.	Sample Volume can be set in increments of 0.1 µL. Dilution is Deionized (DI) water (0 or 10 µL) dispensed for a sample dilution following the sample dispense. If Dilution is set to 0 µL, then an extra 2.9µL of sample is aspirated for dispensing accuracy.
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, or 100	Defines the automatic pre-dilution to be performed on the analyzer in a dilution cuvette with sample and deionized water or other diluent. Refer to Pre-Dilution Rate Volumes in Repeat Specific Screen for a list of the sample volume required for each pre-dilution rate. The test sample volume is dispensed from the dilution cuvette into the reaction cuvette.
Reagent Volume (for all markets except Japan)	R1(R1-1): 15 to 250 µL R1-2: 0, 5, 15 to 20 µL R2(R2-1): 0, 15 to 250 µL	Reagent volumes can be set in increments of 1.0 µL. The total Reagent Volume and Dilution is a maximum of 250 µL.
Dilution (for all markets except Japan)	R1(R1-1): 0, 10 to 235 µL R1-2: 0, 10 to 20 µL R2(R2-1): 0, 10 to 235 µL	
Reagent Volume (for Japan only)	R1(R1-1): 10 to 250 µL R1-2: 0, 5, 10 to 20 µL R2(R2-1): 0, 10 to 250 µL	
Dilution (for Japan only)	R1(R1-1): 0, 10 to 240 µL R1-2: 0, 10 to 20 µL R2(R2-1): 0, 10 to 240 µL	
Wave Length Pri.	340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm	
Wave Length Sec.	None, 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm	

Table 2.8 General Screen Description (Continued)

Item	Contents	Input Notes
Method	END, RATE, FIXED, END1, RATE1, FIXED1	The 1 at the end of a method name indicates a method not using a reagent blank correction. The reagent blank is not subtracted from the measuring points.
Reaction Slope	+, -	+ used for an increasing reaction curve - used for a decreasing reaction curve
Measuring Point-1 Measuring Point-2	END method, FIXED method • First: 0 to 26 • Last: 1 to 27 RATE method • First: 0 to 25 • Last: 1 to 27	Self blank: the absorbance of Measuring Point-2 data (caused by sample) is subtracted from Measuring Point-1 data (reaction data).
Linearity Limit	0 to 100	A check for Rate Methods to confirm if the reaction is non-linear caused by exceeding the defined % variance or OD limits between photometer read points. A * flag is generated if the limits are exceeded.
Lag Time Check	YES/NO	Yes can only be set for Rate Methods. Lag time is the time after all reagents have been added to the sample and before any read points are taken to determine the reaction rate.
OD Limit	-2.0000 to 3.0000	Programming is only available for Rate and Fixed methods. Generates a B flag for less than the minimum OD and a D flag for greater than the maximum OD.
Reagent OD Limit	-2.0000 to 3.0000	Reagent blank OD limits at the first and last read points. A u or U flag is generated if the reagent OD is under the acceptable limit. A y or Y flag is generated if the reagent OD is over the acceptable limits.
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	Enter a 7-digit numerical value, not including sign and decimal point. Dynamic Range is the range the analyzer can measure for a reagent. If the range is exceeded, F (over) or G (under) flag is generated. If a concentration value cannot be calculated, the OD value is used to indicate if the dynamic range was exceeded. If the OD value is greater than the OD of the upper limit of the dynamic range, an Fx flag is generated. If the OD value is less than the OD of the lower limit of the dynamic range, an Gx flag is generated. Set the decimal place in the Range tab.

Table 2.8 General Screen Description (Continued)

Item	Contents	Input Notes
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	The Correlation Factor corrects the concentration value with the equation Y = AX + B. The Correlation correction is performed after checking the dynamic range. If a Correlation Factor and a Factor for Maker are programmed, the results are calculated with both factors.
Factor for Maker	Display only	The Factor for Maker coefficient corrects the concentration value with an equation of Y=AX+B. The Factor for Maker correction is performed before checking the dynamic range. If a Correlation Factor and a Factor for Maker are programmed, the results are calculated with both factors.
Onboard Stability Period	Days (0 to 999) and hours (0 to 23)	The onboard stability period starts when the reagent check is performed, regardless of the reagent being used or not.
LIH Influence Check	YES/NO	LIH Influence Check only displays if the optional Test Specific LIH is enabled in System Maintenance by Beckman Coulter. Yes: Flags the result with l, i, or h if the level of LIH exceeds the test's specific limits. An n flag is generated if LIH testing is not performed on the sample. No: Test specific LIH is not evaluated for the test.
Lipemia	+, ++, +++, ++++, +++++	If LIH Influence Check is Yes, program test specific LIH criteria from the test specific chemistry setting sheet.
Icterus		
Hemolysis		
Change Reagent Type (F5)	Select **R1-2** to program a 3-part reagent.	
Set Common Reagent (F6)	Program the R1-2 of a 3-part reagent to be used for two tests.	
List Display (F7)	Displays a list of all Specific Test Parameters	Use the list to confirm parameters. Six tests display at a time. Select the sample type to display from **Type**.

Linearity Limit

Linearity Calculation Method:

(|a-b|/(|c|* 0.5))*100 = Linearity limit value (parameter)

a: OD value change quantity of the first half of the reaction curve

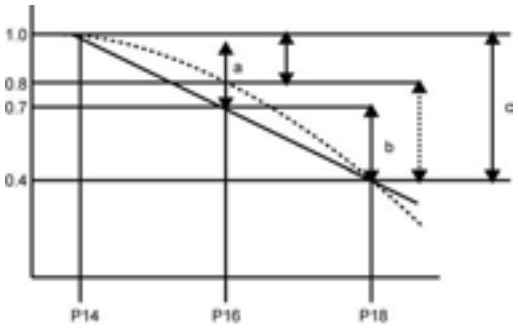
b: OD value change quantity of the last half of the reaction curve

c: OD value change quantity of the reaction curve (between photometry start point and end point)

| |: Absolute value

- In the case of a straight line (similar to the solid line shown), the values of a and b become almost the same and linearity becomes 0%.
- In the case of a curve (similar to the dotted line shown), a becomes smaller and b becomes larger, and linearity becomes 67% approximately.

Figure 2.12 Linearity Calculation Method



Lag Time Check

If Lag Time Check is Yes, the following check is performed:

- The Predicted maximum reaction OD (delta OD) is calculated to the concentration.
- The converted concentration is checked versus the dynamic range.

  If more than two points of the measurements fall within the dynamic range, the Lag Time Check occurs using the measurement results. When the measurement results failed the Lag Time Check, an E flag is generated.

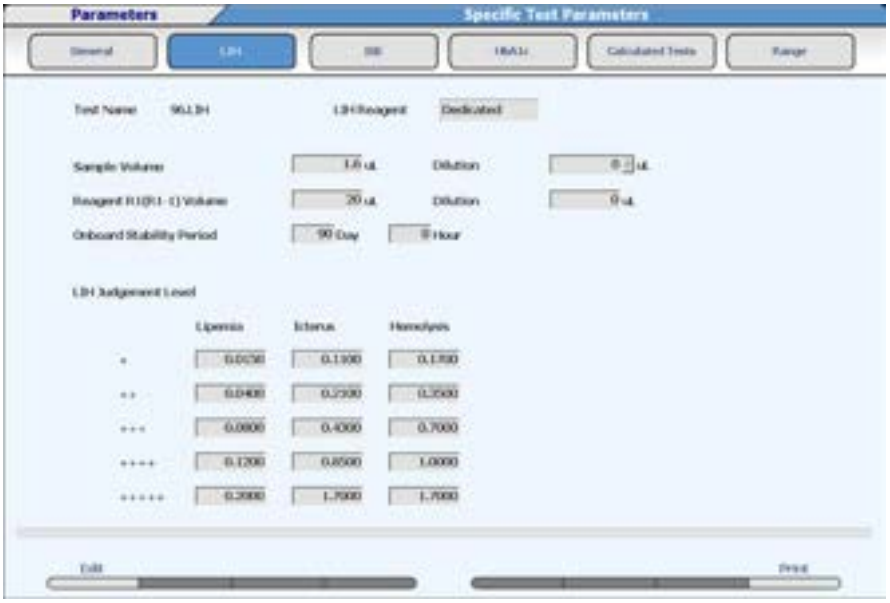
  If only two points or less of the measurements fall within the dynamic range, the OD is calculated using the measurement results obtained before the measuring points programmed in **Specific Test Parameters**, for example P11.

LIH Screen

If LIH is assigned to Test No. 96 LIH using Dedicated LIH Reagent or saline, program the LIH parameters. Refer to Test Name Screen.

Select **Menu List > Parameters > Specific Test Parameters > LIH**.

Figure 2.13 Specific Test Parameters: LIH Screen



NOTE

LIH Judgement Level

The system is programmed with OD limits to flag samples for lipemia, icterus, and hemolysis. Each sample prints with LIP (lipemia), ICT (icterus), and HEM (hemolysis) tests with normal, +, ++, +++, ++++, +++++.

NOTE

LIH Reagent (OSR62166) is the only validated reagent for sample and test specific LIH testing.

Table 2.9 LIH Screen Description

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	Dedicated or Non-Dedicated displays from **Common Test Parameters > Test Name**. Sample Volume, Dilution, Reagent Volume, and Onboard Stability Period can only be entered if LIH is Dedicated. If LIH is Non Dedicated, the parameters from the on-board test used for LIH analysis are used.

Table 2.9 LIH Screen Description (Continued)

Item	Contents	Input Notes
Sample Volume and Dilution (for all markets except Japan)	• If Dilution is 0 µL, then the Sample Volume can be set from 1.6 to 25.0 µL. • If Dilution is 10 µL, Sample Volume can be set from 1.6 to 20.0 µL. • The minimum Sample Volume is 1.6 µL.	In steps of 0.1 µL.
Sample Volume and Dilution (for Japan only)	• If Dilution is 0 µL, then the Sample Volume can be set from 1.0 to 25.0 µL. • If Dilution is 10 µL, Sample Volume can be set from 1.0 to 20.0 µL. • The minimum Sample Volume is 1.0 µL.	In steps of 0.1 µL.
Reagent R1 (R1-1) Volume and Dilution (for all markets except Japan)	• If Dilution is 0 µL, then the Reagent Volume can be set from 15 to 250 µL. • If Dilution is 10 µL, Reagent Volume can be set to 0, 10 to 235 µL.	In steps of 1 µL. The total Reagent Volume and Dilution is a maximum of 250 µL.
Reagent R1 (R1-1) Volume and Dilution (for Japan only)	• If Dilution is 0 µL, then the Reagent Volume can be set from 10 to 250 µL. • If Dilution is 10 µL, Reagent Volume can be set to 0, 10 to 240 µL.	In steps of 1 µL. The total Reagent Volume and Dilution is a maximum of 250 µL.
Onboard Stability Period	Days (0 to 999) and Hours (0 to 23)	
LIH Judgement Level	The judgement level is programmed separately for Lipemia, Icterus, and Hemolysis.	Refer to the LIH chemistry setting sheet or enter values established by the facility. LIH Reagent with LIH parameters from the chemistry setting sheet is the only validated option for test specific LIH.
	+ : 0.0 to 3.0	
	++ : + value to 3.0	
	+++ : ++ value to 3.0	
	++++ : +++ value to 3.0	
	+++++ : ++++ value to 3.0	

ISE Screen

If the ISE option is used, program the operation, dynamic range, and correlation factor for the serum and urine sample types.

Select **Menu List > Parameters > Specific Test Parameters > ISE**.

Figure 2.14 Specific Test Parameters: ISE Screen

NOTE

Sample Volume, Dilution, MID CONC, STD CONC Low, and STD CONC High display the pre-programmed values and cannot be changed.

Program the Dynamic Range and Correlation Factor for Serum and Urine.

Table 2.10 ISE Screen Description

Item	Contents	Input Notes
Operation	Yes or No	Select **Yes** to enable operation for Na, K, and Cl testing for Serum or Urine.
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	Refer to the ISE Reagents Instructions for Use. Enter a 7-digit numerical value, not including the sign and decimal point. The number of decimal places is programmed in the Range tab.
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Correlation value = A x (measuring value) + B. Enter a 7-digit numerical value, not including sign and decimal point.

HbA1c Screen

CAUTION

This function is intended for use with AU reagents only. Use of another manufacturer reagent other than AU can cause incorrect diagnosis results.

Operation of the three tests 100.DENAT, 101.T-Hb, and 102.HbA1c and part of the specific test parameters are pre-programmed and cannot be changed.

Program HbA1c Tests

Select **Menu List > Parameters > Specific Test Parameters > HbA1c**.

Figure 2.15 Specific Test Parameters: HbA1c Screen

Table 2.11 HbA1c Screen Description

Item	Contents	Input Notes
Operation	Yes or No	Select **Yes** to enable operation for HbA1c analysis. This enables operation for tests 100. DENAT, 101. T-Hb, and 102. HbA1c. It is not possible to enable 100. DENAT, 101. T-Hb, or 102. HbA1c individually.
Reagent OD Limit	First Low:-2.0000 to 3.0000 High:-2.0000 to 3.0000 Last Low:-2.0000 to 3.0000 High:-2.0000 to 3.0000	

Table 2.11 HbA1c Screen Description (Continued)

Item	Contents	Input Notes
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Correlation value = A x (measuring value) + B. The Correlation correction is performed after checking the dynamic range.
Factor for Maker	Display only	The Factor for Maker coefficient revises concentration value with an equation of Y=AX+B. The Factor for Maker correction is performed before checking the dynamic range. If a Correlation Factor and a Factor for Maker are programmed, the results are calculated with both factors.
Onboard Stability Period	Days (0 to 999) and Hours (0 to 23)	
Correlation Factor for HbA1c%	A: -9999999 to 9999999 B: -9999999 to 9999999	Correlation value = A x (measuring value) + B.

Calculated Tests Screen

Program the calculation parameters for a maximum of 20 calculated tests. The calculated test name must be defined in **Common Test Parameters > Test Name > Calculated Tests (F6)** before it is available to enter parameters. When programmed, calculated tests are performed and print automatically when all the tests in the calculation are ordered (requisitioned) and run simultaneously. A reference range can be assigned to the calculated test in the Range screen.

To program the calculated test name, refer to Test Name Screen.

Select **Menu List > Parameters > Specific Test Parameters > Calculated Tests**.

Figure 2.16 Specific Test Parameters: Calculated Tests Screen

Table 2.12 Calculated Tests Screen Description

Item	Contents	Input Notes
Calculated Test Name	Calculated test number 1 to 20	A calculated test name must be assigned to a calculated test number in **Common Test Parameters > Test Name > Calculated Tests (F6)** before it is available.
Type	Serum, Urine, Other-1, or Other-2	
Test Name	Select the tests involved in the calculation at A, B, C, D, and E.	A maximum of 5 tests can be set.
Constant	If Calculate Type is set to Value, enter a numerical constant (-999999 to 9999999) for a through d. If Calculate Type is set to Patient Inf.-1 through -6, then Patient Information 1 to 6 defined as a Numeric Attribute can be used.	A maximum of 4 constants can be set. Enter a 7-digit numerical value, not including sign and decimal point. Patient Information can be programmed in **Menu List > System > Format > Requisition Format**. Program Attribute to Numeric Attribute to allow entering a numerical value as a patient demographic used as a constant a through d in the calculated test.
Formula	Calculated test formula	A maximum of 20 characters. Combination of +-*/()ABCDEabcd

Table 2.12 Calculated Tests Screen Description (Continued)

Item	Contents	Input Notes
QC Perform	Yes, No	If Yes is selected, a QC range can be programmed for the calculated test in **QC Parameters**.

NOTE

The calculation formula uses A to E, arithmetic calculation, and the coefficients a to e. The coefficients can use numerical patient information (weight etc.).

If Yes is selected at QC Perform, a QC range can be programmed for the calculated test in **QC Parameters**. For example, the QC may be in range for TP and ALB. If an albumin/globulin ratio calculation is performed with a QC range programmed, the calculated test QC can be out of range.

A calculated test is repeated if the calculated test generates a repeat flag, or if all tests that are part of the calculated test generate a repeat flag. A calculated test can be programmed to generate ph, pl, P, N, H, L, J, and K flags.

Color Items, Blank Items, LIH, calculated tests, and HbA1c tests numbers 100, 101, and 102 cannot be used in the formula.

Range Screen

Program the reference range values for tests.

Data judgment is performed according to the quantitative method by values or according to the qualitative method by flags.

Select **Menu List > Parameters > Specific Test Parameters > Range**.

Figure 2.17 Specific Test Parameters: Range Screen

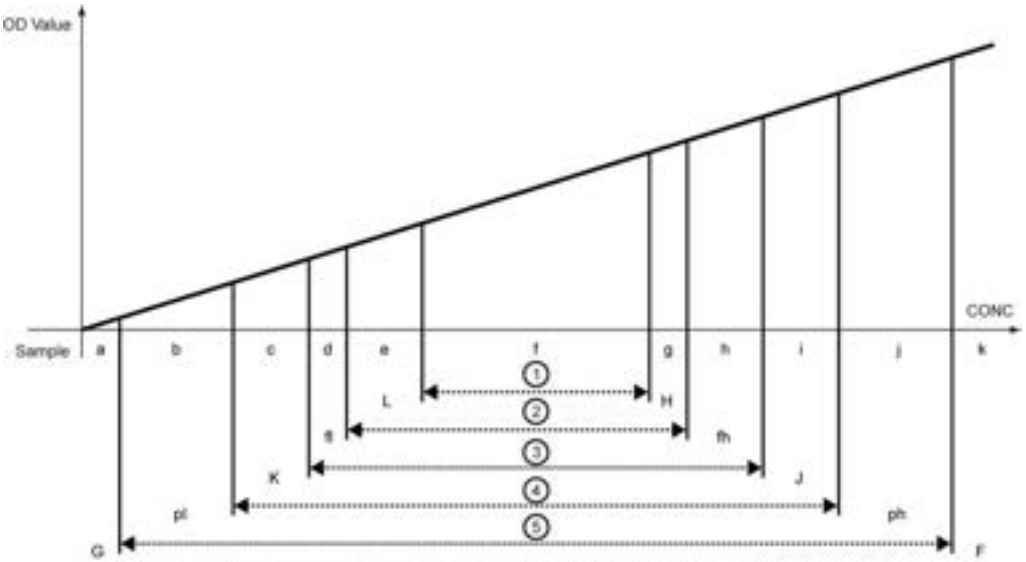
Table 2.13 Range Screen Description

Item	Contents	Input Notes
Test Name	A test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Value/Flag	Value or Flag. If Flag is programmed, then enter a number (-999999 to 9999999) for Level Low and High.	Value: Program a normal reference range in Specific Ranges (1 to 8) to generate L (low) or H (high) flags on tests. Specific reference ranges can be programmed by sex and age. Flag: Program a range in Level Low and High to generate a P (positive) flag if over the High limit, or N (negative) flag if below the Low limit. Typically this is programmed for qualitative drugs of abuse testing.
Panic Value	Enter a number (-999999 to 9999999) for Low and High.	Enter a user-defined panic range. A pl flag is generated if the result falls below the Low limit, and a ph flag is generated if the result falls above the High limit. An audible alarm is also generated if the panic range is exceeded.
Unit	The units to print on a report.	
Specific Ranges 1 to 8	Low: -9999999 to 9999999 High: Low value to 9999999	A 7-digit numerical value, not including sign and decimal point. The number of decimal places is programmed in **Decimal Places (F5)**. Program ranges to generate L flags for data less than the Low limit or H flags for data greater than the High limit. 1 to 6: Select the check box to enter normal ranges that are age and gender specific. Patient demographics must be programmed to use this feature. 7: No demographics: Enter a generic normal range. This range is used for the sample without patient demographic information (age and gender). 8: Not within expected values: This range is used for the sample with patient demographic information (age or gender), but the age or gender information did not meet the age and gender defined in the specific range 1 to 6.
Decimal Places (F5) displays after selecting Edit (F1).	0 to 4	The decimal places entered affect software prompts and printed results.

Figure 2.18 Set Decimal Places Dialog

Programmable Ranges in General, ISE, Range, and Repeat Specific Screens to Generate Flags

Figure 2.19 Possible Flags in Order of Increasing OD



1. Normal value range
2. Reflex range
3. Repeat decision range
4. Panic value
5. Dynamic range

- Up to 4 flags may be attached to abnormal data according to priority.

Sample	a	b	c	d	e	f	g	h	i	j	k
Flag	G,pl, L,K, (fl)	pl,L, K,fl	L,K, fl	L,fl	L	none	H	H,fh	H,J, fh	ph,H, J,fh	F,ph, H,J,(fh)

- As sample f is within the normal value range, it has no flag.
- The four flags with the highest priorities are displayed on the monitor and are printed out.
- Online parameters can be programmed to transmit two or four result flags. Refer to Online Menu for additional information.
- The repeat decision range and reflex range are programmed within the dynamic range.

Table 2.15 Screen to Program Each Range

Contents	Screen
Normal Reference range	**Parameters > Specific Test Parameters > Range**
Panic range	**Parameters > Specific Test Parameters > Range**

Table 2.15 Screen to Program Each Range (Continued)

Contents	Screen
Dynamic range	**Parameters > Specific Test Parameters > General** and **ISE**
Repeat Decision range	**Parameters > Repeat Parameters > Repeat Specific**
Reflex range	**Parameters > Repeat Parameters > Repeat Specific**

Repeat Parameters Menu

The AU680 allows either manual or automatic repeat sample analysis. This section describes how to program the repeat mode.

Normal repeat:

Analysis is performed with the same parameters used for the initial analysis.

Repeat run with dilution:

Analysis is performed with a pre-dilution or a smaller sample volume than the initial run. Pre-dilution means a dilution cuvette of sample and diluent is made on-board the analyzer. The sample is dispensed from the dilution cuvette into the reaction cuvette.

1. Reduce the sample dispense volume.
2. Increase the dilution ratio.

Repeat run with condense:

Analysis is performed with a larger sample volume than the initial analysis.

1. Increase the sample dispense volume.
2. Reduce the dilution ratio.

WARNING

- **Whenever parameters are user-defined, the operator must confirm that the results meet their requirements for test performance including reproducibility and accuracy.**
- **The measured value with the repeat dilute or condense sample volume and dilution ratio should be well within the dynamic range of the test for best performance.**
- **When possible, change either the sample volume or the dilution ratio and avoid changing both for dilution or condense.**

NOTE

If the AU680 is connected to a laboratory automation system:

- Samples transported from the laboratory automation system query the laboratory information system for the test order (requisition) and required dilution. The sample is processed as an original sample.

- Samples processed on the STAT table are processed as repeat samples, and can query the laboratory information system or use repeat parameters for the repeat order (requisition).

Repeat Common Screen

Data Flag Tab

Select **Menu List > Parameters > Repeat Parameters > Repeat Common > Data Flag**.

Figure 2.20 Repeat Common: Data Flag Tab

Table 2.16 Data Flag Tab Description

Item	Contents	Input Notes
Auto Repeat Requisition	Yes or No	Select **Yes** to generate automatic repeat requisitions. If **No** is selected, repeat requisitions are not made, and the repeat requisitions must be retrieved manually in **Routine > Repeat Run > Repeat Order > Regenerate Repeat Req. (F2)**.
Repeat Data Over-Writes Original Data Automatically	Yes or No	Select **Yes** to automatically over-write original data with repeat data. Select **No** to review the original data and repeat data prior to over-writing.
Repeat when any selected flag occurs.	Select (highlight) the flags to generate a repeat requisition.	A repeat requisition is generated when any of the highlighted flags are generated.
Repeat when all selected flags occur.	Select (highlight) a flag to generate a repeat requisition.	A repeat requisition is generated only when all highlighted flags are generated.
Repeat with diluent when any selected flag occurs.	Select (highlight) a flag to generate a repeat requisition.	A repeat dilution requisition is generated when any of the highlighted flags are generated.

Table 2.16 Data Flag Tab Description (Continued)

Item	Contents	Input Notes
Repeat with diluent when all selected flags occur.	Select (highlight) a flag to generate a repeat requisition.	A repeat dilution requisition is generated only when all highlighted flags are generated.
Repeat with condense when any selected flag occurs.	Select (highlight) a flag to generate a repeat requisition.	A repeat condense requisition is generated when any of the highlighted flags are generated.
Repeat with condense when all selected flags occur.	Select (highlight) a flag to generate a repeat requisition.	A repeat condense requisition is generated only when all highlighted flags are generated.

The same flag can only be selected for one of the following options. The last option selected is programmed.

- Repeat when any selected flag occurs
- Repeat with dilute when any selected flag occurs
- Repeat with condense when any selected flag occurs

Selecting exactly the same combination of flags in these three options generates an error message when **Confirm (F1)** is selected:

- Repeat when all selected flags occur
- Repeat with diluent when all selected flags occur
- Repeat with condense when all selected flags occur

Select **Cancel** to resolve the error. If **OK** is selected with the error unresolved, the analyzer cannot start analysis.

For more information on flags, refer to the AU680 Instructions for Use.

All tests programmed as part of a calculated test are repeated if any test in the calculation generates a repeat flag. If the flag is programmed to repeat with a dilution, then that test is diluted. Other tests in the calculation without repeat flags repeat with original sample volumes.

Group Tab for Reflex Testing

Program a Deciding Test and a maximum of five Related Tests as a group for reflex testing. When the Deciding Test has resulted in a repeat, fl, or fh flag, the Related Tests are automatically ordered (requisitioned) for repeat analysis. The Deciding Test is also ordered (requisitioned) with a repeat flag, but is not ordered (requisitioned) with a fl or fh flag.

For example, if ALB is programmed as the Deciding Test and TP as the Related Test, both ALB and TP are ordered (requisitioned) for repeat analysis when a repeat flag has been generated on ALB. However, only TP is ordered (requisitioned), and ALB is not ordered (requisitioned) when a fl or fh flag has been generated on ALB.

A maximum of 10 repeat run groups can be programmed.

NOTE

A fh or fl flag is generated if a result does not fall within the Reflex Range programmed in **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Select **Menu List > Parameters > Repeat Parameters > Repeat Common > Group**.

Figure 2.21 Repeat Common: Group Tab

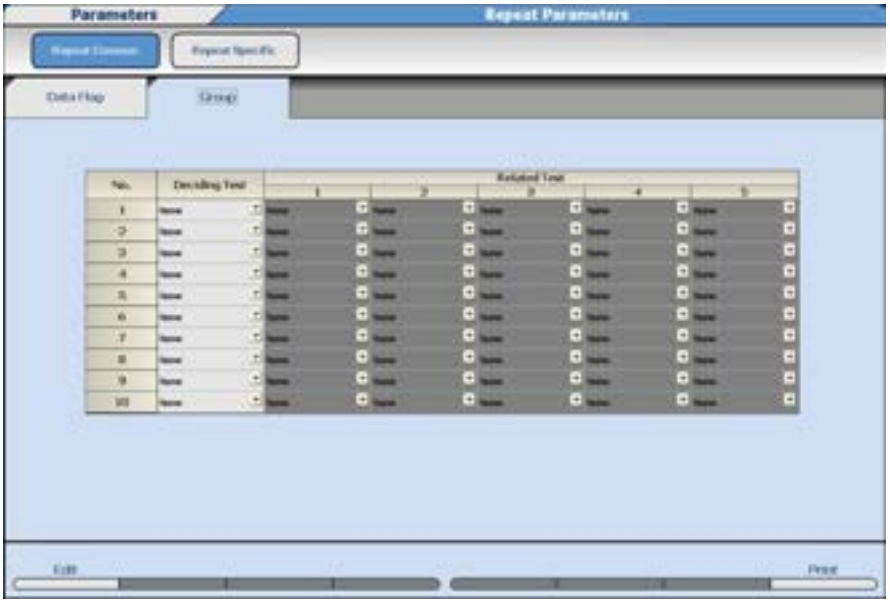


Table 2.17 Group Tab Description

Item	Contents	Input Notes
Deciding Test	Name of test	Generates an automatic repeat order (requisition) for the Related Tests when resulting in a repeat, fl, or fh flag. The Deciding Test is also ordered (requisitioned) with a repeat flag but is not ordered (requisitioned) with fl or fh flag.
Related Test	Name of test	Automatically ordered (requisitioned) for repeat when the Deciding Test has resulted in a repeat, fl, or fh flag.

Repeat Specific Screen

Program the sample volume, diluent volume, and pre-dilution rate for a normal repeat run, repeat run with dilution, and repeat run with condense.

Select **Menu List > Parameters > Repeat Parameters > Repeat Specific**.

Figure 2.22 Repeat Parameters: Repeat Specific Screen

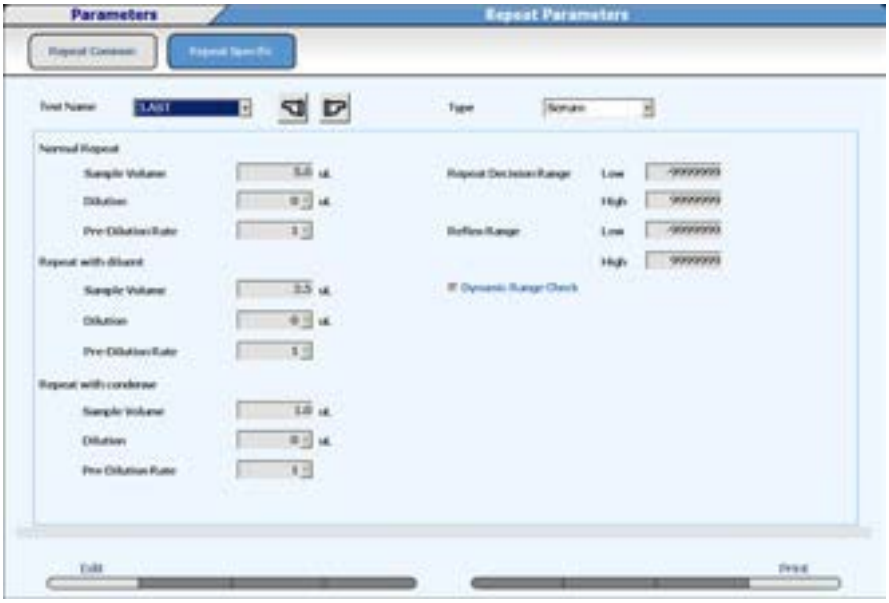


Table 2.18 Repeat Specific Screen Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, and Whole Blood	
Normal Repeat • Sample Volume • Dilution • Pre-Dilution Rate	Sample Volume, Dilution, and Pre-Dilution Rate display from **Specific Test Parameters**.	
Repeat with diluent and Repeat with condense (for all markets) • Sample Volume • Dilution	• If Dilution is 0 µL, then the Sample Volume can be set from 1.0 µL to 25.0 µL. • If Dilution is 10 µL, then the Sample Volume can be set from 1.0 µL to 20.0 µL. • Minimum Sample Volume is 1.0 µL.	Sample Volume can be programmed in 0.1 µL increments. Dilution can be programmed to 0 µL or 10 µL. Deionized water is dispensed from the sample probe following the sample dispense.

Table 2.18 Repeat Specific Screen Description (Continued)

Item	Contents	Input Notes
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, 100	A dilution cuvette is made on-board the analyzer with sample and diluent. Refer to the table below for sample and diluent dispense volumes. The Repeat with diluent Sample Volume is then dispensed from the dilution cuvette into the test cuvette, and results are calculated.
Repeat Decision Range Low and High	A number (-999999 to 9999999)	A user-defined range to generate a repeat order (requisition). Results below the Low limit generate a K flag. Results above the High limit generate a J flag.
Reflex Range Low and High	A number (-999999 to 9999999)	A user-defined range to generate the reflex testing. If a result does not fall within this range, a fh or fl flag is generated on the test. (A fh flag is generated when the result is above High, and fl when below Low.). This range is used to automatically order (requisition) Related Tests when the Deciding Test has resulted in either of these flags. Program the Deciding Test and Related Tests in **Menu List > Parameters > Repeat Parameters > Repeat Common > Group**.
Dynamic Range Check	Checked or Not Checked	If Checked, when a test generates F, G, Fx, or Gx and the corresponding flag is selected in **Repeat Common**, the test is repeated. If Not Checked, when a test generates F, G, Fx, or Gx and the corresponding flag is selected in **Repeat Common**, the test is not repeated. The default setting is Checked.

Pre-Dilution Rate Volumes

Refer to the Pre-Dilution Rate Item in the preceding table for information on pre-dilution rate.

Table 2.19 Pre-Dilution Rate Volumes

Pre-Dilution Rate	Sample Volume (µL)	Dilution Volume (µL)	Volume in Cuvette (µL)
3	50	100	150
5	30	120	150
10	20	180	200
15	15	210	225
20	10	190	200
25	8	192	200

Table 2.19 Pre-Dilution Rate Volumes (Continued)

Pre-Dilution Rate	Sample Volume (µL)	Dilution Volume (µL)	Volume in Cuvette (µL)
50	4	196	200
75	3	222	225
100	2	196	200

Calibration Parameters Menu

Program the calibrators used for calibration analysis and the calibration parameters.

Typically calibrators are assigned to positions in the yellow rack, or calibrator barcode operation is enabled and the calibrators are placed in any position in the yellow rack.

Calibrators can be assigned to positions on the STAT table, or calibrator barcode operation can be enabled and the calibrators can be placed in any position on the STAT table.

NOTE

When the AU680 is connected to a laboratory automation system, calibration must be performed with bar codes from the STAT table.

CAUTION

Incorrect calibration parameters cause errors in analysis results, and can cause misdiagnosis. Specific test calibration parameter settings should be visually confirmed against the published settings, and through analysis using Quality Control materials.

For more information on displaying a list of set values, refer to Calibration Specific Screen.

Calibrators Screen

Program a maximum of 200 calibrators required for specific tests programmed on the system. Calibrators are programmed to a Type (Serum, Urine, Other-1, Other-2, or Whole Blood) by Beckman Coulter determined by laboratory requirements.

Select **Menu List > Parameters > Calibration Parameters > Calibrators**.

Figure 2.23 Calibration Parameters: Calibrators Screen

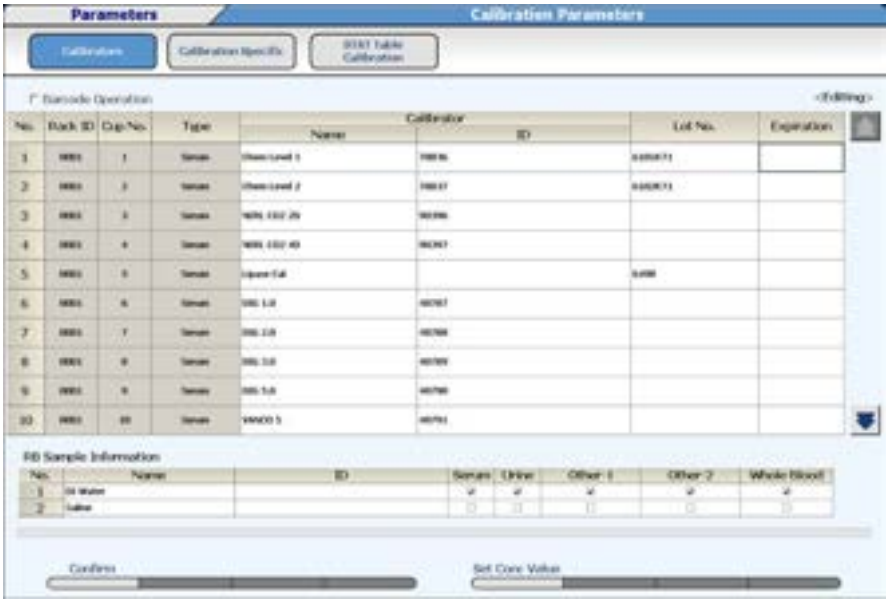


Table 2.20 Calibrators Screen Description

Item	Contents	Input Notes
Barcode Operation	Check or No Check	If Barcode Operation is selected, calibrator IDs are assigned to calibrator material and calibrators can be placed in any position in the yellow rack. If Barcode Operation is not selected, calibrators are assigned to positions in the yellow rack.
Name	Calibrator name	A maximum of 20 characters.
ID	Calibrator ID (bar code)	A maximum of 26 alphanumeric characters for the calibrator ID when Barcode Operation is selected.
Lot No.	Calibrator lot number	A maximum of 15 alphanumeric characters.
Expiration	Calibrator expiration date	Enter a date, for example YYYY/MM/DD.
RB Sample Information	Reagent blank No., Name, ID, and Sample Type.	Two types of reagent blank material (No. 1 and No. 2) can be defined. All tests currently use deionized water, typically assigned to position 1. Check Serum, Urine, Other-1, Other-2 and Whole Blood for No. 1. Enter a reagent blank name (a maximum of 20 characters), typically DI water. Enter a reagent blank ID (a maximum of 26 characters) if Barcode Operation is selected.
Set Conc Value (F5)	Calibrator concentration	Use to enter calibrator concentrations for a new lot number. For tests with a multi-point calibration curve, confirm the concentration of all calibrator levels.

NOTE

The reagent blank can be set for each sample type.

When No.1 is selected, set the cup in the first cup position of the blue rack or the RB1 position on the STAT table.

When No.2 is selected, set the cup in the second cup position of the blue rack or the RB2 position on the STAT table.

When the AU680 is connected to a laboratory automation system, reagent blanks are performed from the STAT table. Set the reagent blank No. 1 in position RB1 and reagent blank No. 2 in position RB2 on the STAT table.

Calibration Specific Screen

Program all specific calibration parameters for each test. Program and confirm the information from the test's chemistry setting sheet.

General Tab

Select **Menu List > Parameters > Calibration Parameters > Calibration Specific**.

Figure 2.24 Calibration Specific: General Tab

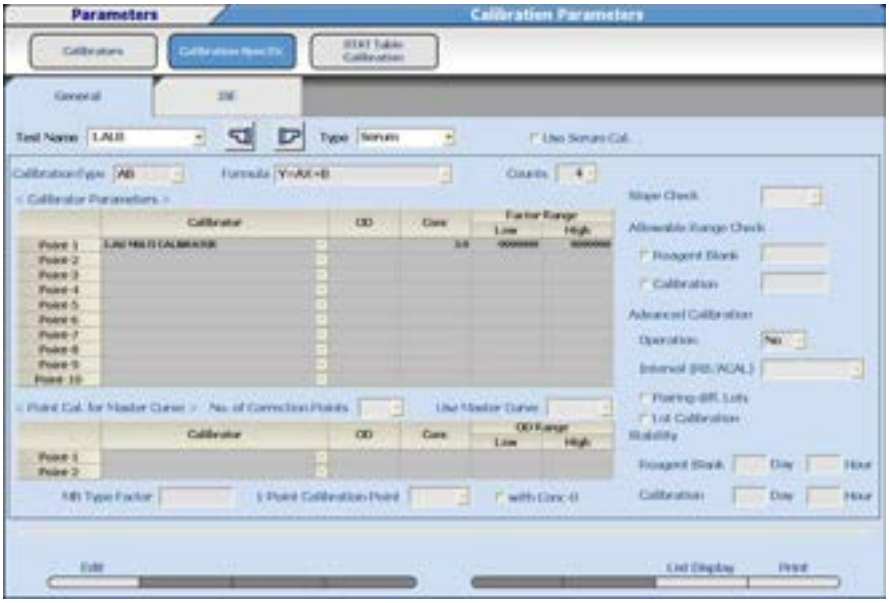


Table 2.21 General Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	

Table 2.21 General Tab Description (Continued)

Item	Contents	Input Notes
Use Serum Cal.	Check or no check	Select this option to use the Serum calibration curve for the Urine, Other-1, or Other-2 test. The Urine, Other-1, or Other-2 test is not calibrated.
Calibration Type	MB to 7 MB, AA, AB to 7 AB, 4 MC to 10 MC	Enter the Calibration Type from the chemistry setting sheet. For a description of the different calibration types, refer to Summary of Calibration Types.
Formula	Interpolation formula for the calibration curve.	Select the formula from the chemistry setting sheet. The formulas that can be selected for a test are limited by the calibration type.
Counts	1, 2, 3, or 4	The quantity of reagent blank and calibration replicates used for calculation. If 1 is set, the reagent blank or calibrator OD is used for calculation. If 2 is set, the mean value of the replicates is used. If 3 is set, the mean value of the two closest replicates is used. If 4 is set, the highest and lowest replicate values are discarded, and the mean value of the two replicates is used.
Slope Check	+ or -	Refer to the chemistry setting sheet. For multi-point calibrations (AA and 2 AB to 7 AB) the software checks to verify all OD values are increasing (+) or decreasing (-).
Allowable Range Check	OD value (0.0000 to 3.0000)	Refer to the chemistry setting sheet. An acceptable dispersion of OD values (OD delta check) for the reagent blank and calibration for AA, AB to 7AB, and 4MC to 10MC.
Advanced Calibration Operation	Yes or No	Refer to the chemistry setting sheet. Advanced calibration allows reagent blank and calibration for up to 5 bottles or lot numbers of the same test.
Advanced Calibration Interval (RB/ACAL)	Lot/Lot Bottle/Lot Bottle/Bottle Lot/None Bottle/None	

Table 2.21 General Tab Description (Continued)

Item	Contents	Input Notes
Pairing diff. Lots	Check or no check	No check: The system does not process a test when R1 and R2 have different lot numbers and Advanced Calibration is in use. Check: The system processes a test when R1 and R2 have different lot numbers and Advanced Calibration is in use. Program Advanced Calibration Interval (RB/ ACAL) to Bottle/Bottle or Bottle/None to enable the Pairing diff. Lots option. ⚠ **CAUTION** **Do not select the Paring diff. Lots box for Beckman Coulter reagents.**
Lot Calibration	Check or no check	Only available when Advanced Calibration is set to Lot/Lot. Affects the reagent blank and calibration stability when a second bottle of reagent with the same lot is placed on the system. If checked, when the second bottle of reagent is placed on the system, the calibration factor from the first bottle of reagent (base factor) is used for the second bottle of reagent. The reagent blank and calibration stability for the first bottle continues to be tracked, and the reagent blank and calibration stability for the second bottle is set to the programmed stability in **Calibration Specific**. If unchecked, when the second bottle of reagent is placed on the system, the reagent blank and calibration stability is tracked at the first bottle's remaining stability period for both bottles.
1-Point Calibration Point	Calibrator Point-1 to Point-7	For a multi-point calibration, enter the calibrator number to adjust the multi-point calibration curve by a single point.
with Conc-0	Check or no check	Enter a check for a multi-point calibration to include the zero concentration. If 1-Point Calibration Point is used and zero concentration is the origin, check with Conc-0 and enter the calibrator number in 1-Point Calibration Point.
Calibrator	Calibrator name	The calibrator material must be programmed in **Calibrators** before it is available.

Table 2.21 General Tab Description (Continued)

Item	Contents	Input Notes
OD	OD value	Enter the OD (-2.0000 to 3.0000) for calibration types 2 MB to 7 MB.
Conc	Calibrator concentration	A maximum of 9 digits including the decimal point and sign from -99999999 to 999999999.
Factor Range or OD Range	OD range: -2.0000 to 3.0000 Factor range: -9999999 to 9999999	Refer to the chemistry setting sheet. When the calibration type is 2AB to 7AB, an OD Range is programmable. When the calibration type is AB or AA, a Factor Range is programmable. A Calibration Factor/OD Range alarm is generated if the range is exceeded.
<Point Cal. For Master Curve>	Calibrator, Conc, OD Range	A master curve using a one or two point calibration can be used to update a multi-point calibration. Refer to the chemistry setting sheet. The reagent bottle has a 2-dimensional ID that contains the OD values for each lot number for the master curve concentrations. These values are scanned in with the hand-held bar code reader in **Reagent Management**.
MB Type Factor	MB factor	Refer to the chemistry setting sheet. When the calibration type is MB to 7 MB, enter the MB Type Factor (-99999999 to 999999999).
Stability: Reagent Blank and Calibration	0 to 999 (Day) and 0 to 23 (Hour)	
List Display (F7)	Displays a list of all **Calibration Specific** test parameters.	Use the list to confirm parameters. Select the sample type, and a maximum of six tests to display at a time.

Advanced Calibration

Advanced Calibration allows calibration of up to 5 bottles or lot numbers of the same reagent before the patient run. When the system switches to the new bottle or lot number of reagent, the appropriate calibration curve is used. Advanced Calibration can be used for reagent ID positions, or fixed (assigned) positions. For more information, contact Beckman Coulter.

Lot Calibration

- When Lot Calibration is selected, a maximum of 2 sets of reagent bottles can be used on the system.
- When Lot Calibration is selected, the first successful calibration factor (base factor) is used for both sets of bottles.
- Extra calibrations can be performed on the bottles for verification, and the results can be monitored in **Calibration Monitor**.

When **Use Serum Cal.** is selected, the serum calibration curve is used for Urine, Other-1, or Other-2 sample types.

ISE Tab

Program specific calibration parameters for the ISE tests (Na, K, and Cl).

Select **Menu List > Parameters > Calibration Parameters > Calibration Specific > ISE**.

Figure 2.25 Calibration Specific: ISE Tab

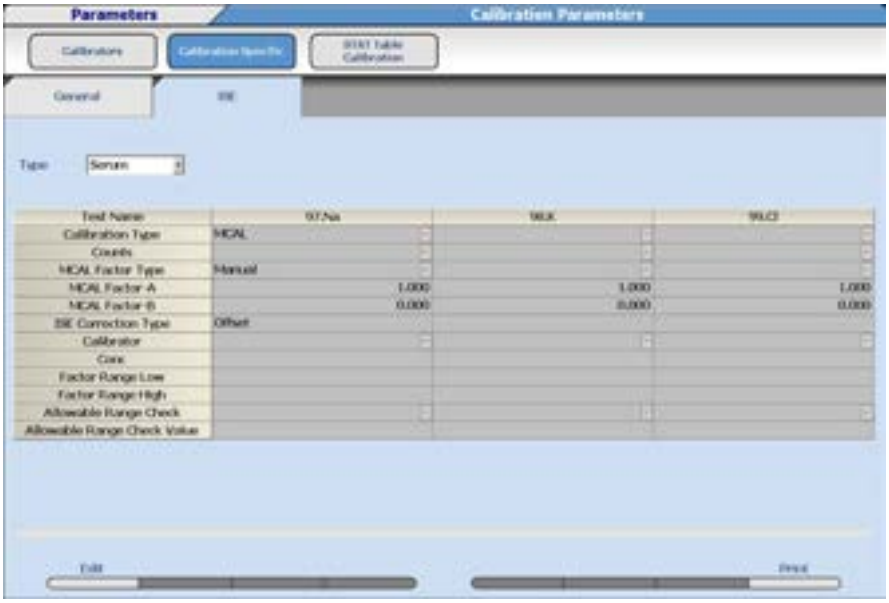


Table 2.22 ISE Tab Description

Item	Contents	Input Notes
Type	Serum or Urine	
Calibration Type	MCAL or ACAL	MCAL means ISE calibration is performed from **ISE Maintenance > Calibration** using the Serum or Urine Standard Solution H and L. ACAL means a calibration is also performed from calibrator material in the yellow rack or STAT table. MCAL or ACAL is common for Na, K, and Cl and cannot be programmed individually by test.
Counts	1 to 4	If ACAL is programmed, select the quantity of calibration replicates.
MCAL Factor Type	Manual or CRS Calibration	CRS Calibration is only available in Japan.

NOTE

It is only possible to program Calibrator, Conc, Factor Range (Low and High), Allowable Range Check, and Allowable Range Check Value if the Calibration Type is programmed to ACAL.

Table 2.23 ISE Tab Description for ACAL

Item	Contents	Input Notes
Calibrator	Calibrator for Na, K, and Cl	Select the calibrator material to use for Na, K, and Cl.
Conc	Calibrator concentration	Enter the calibrator concentration for Na, K, and Cl (-9999999 to 9999999).
Factor Range Low and High	Factor range	Enter the calibration Low factor limit (-9999999) to High factor limit (9999999) for Na, K, and Cl.
Allowable Range Check	Yes or No	Select **Yes** to perform an OD delta check on the calibrator OD values.
Allowable Range Check Value	OD value	If Allowable Range Check is Yes, enter the OD value for the OD delta check.

STAT Table Calibration Screen

All required calibrators and the reagent blank must be programmed for STAT table analysis when using Fixed Positions for calibrators.

- If calibrator barcode operation is in use, the calibrators can be placed in any of the Fixed Positions for calibrators.
- If calibrator barcode operation is not in use, the calibrators must be placed in the Fixed Position specifically programmed for each calibrator.

For information on Fixed Positions, Variable Positions, and Free Positions, refer to Program STAT Table Parameters.

When the AU680 is connected to a laboratory automation system, calibration must be performed with bar codes from the STAT table.

CAUTION

The inside of the STAT table compartment is refrigerated, but it is not intended for long-term storage of samples. Calibrators should be set on the STAT table only for the shortest time required.

For details on programming calibrators and barcode operation, refer to Calibrators Screen.

Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Position and Calibration Specific tabs cannot be programmed when using Free Positions or Variable Positions on the STAT table. These tabs are grayed out after selecting **Edit (F1)**. For information on programming STAT table positions, refer to Program STAT Table Parameters.

Program Calibrators on the STAT Table

Select **Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Position**.

Figure 2.26 STAT Table Calibration: Position Tab

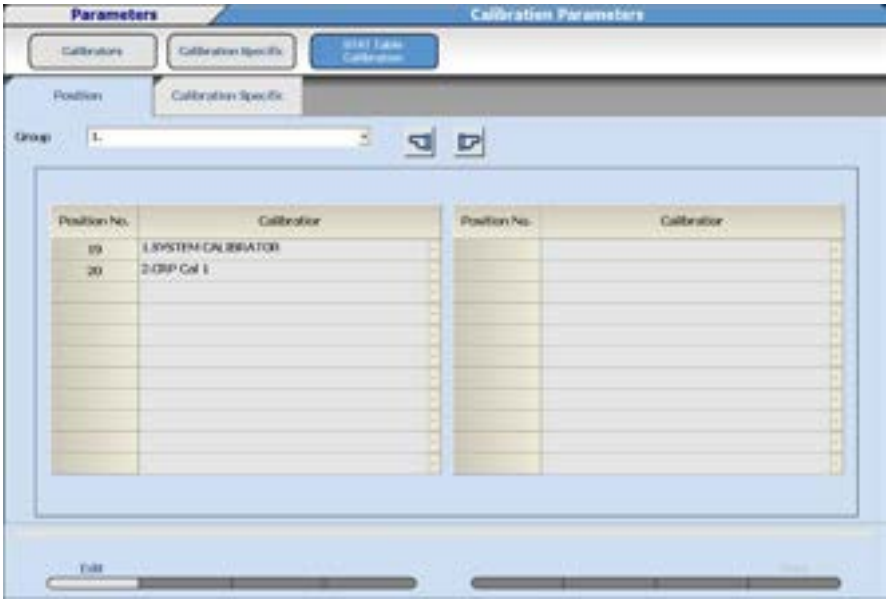


Table 2.24 Position Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **Group 1**, **2**, or **3** to program calibrators on the STAT table for each Group.
Position No. (displays if calibrator Barcode Operation is No) or Number (displays if calibrator Barcode Operation is Yes)	Position 1 to 22	Displays the available calibrator position numbers. Positions are assigned for calibrators in the Analysis mode screen. Refer to Program STAT Table Parameters for programming information.
	Sequential number	Displays the number of available calibrator positions beginning with one. Positions are assigned to calibrators in the Analysis mode screen. Refer to Program STAT Table Parameters.
Calibrator	Calibrator name	Select the calibrator in the Calibrator column.

Program Specific Calibrator Parameters on the STAT Table

Automatic STAT calibration is available by programming **Yes** in the Auto ACAL/RB column. Automatic STAT calibration occurs during sample analysis when the event programmed for Execution Type occurs, and the necessary calibrators are available on the STAT table.

If the automatic STAT calibration is programmed, the amber STAT TABLE LED continuously blinks slowly during analysis.

Program **No** for all items in the Auto ACAL/RB column if automatic STAT calibration is not required.

To perform calibration before QC and sample analysis, refer to Calibration Specific Screen. Advanced Calibration is available for a maximum of five bottle numbers or five lot numbers of reagent.

Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Calibration Specific tab cannot be programmed when using Free Positions or Variable Positions on the STAT table. For information on programming STAT table positions, refer to Program STAT Table Parameters.

Select **Menu List > Parameters > Calibration Parameters > STAT Table Calibration > Calibration Specific**.

Figure 2.27 STAT Table Calibration: Calibration Specific Tab

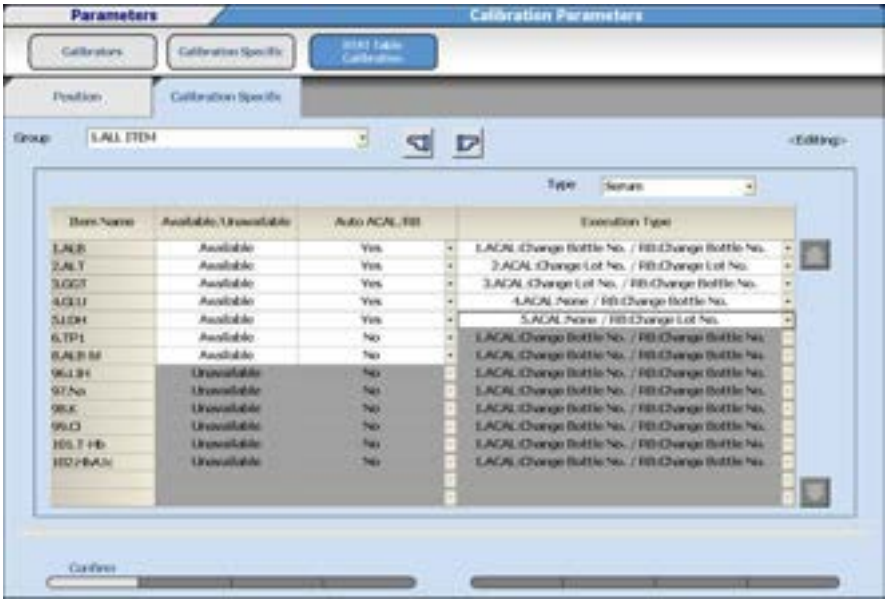


Table 2.25 Calibration Specific Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **Group 1**, **2**, or **3** to program calibrators on the STAT table for the Group.
Type	Serum, Urine, Other-1, or Other-2	Select the sample type from **Type**.
Item Name	Test Name	Displays the test names assigned to Group.
Available/Unavailable	Available or Unavailable	Displays Available if all the necessary calibrators are listed in the Position tab.
Auto ACAL/RB	Yes or No	Yes: The system performs Automatic STAT calibration according to the Execution Type. No: The system does not perform Automatic STAT calibration.

Table 2.25 Calibration Specific Tab Description (Continued)

Item	Contents	Input Notes
Execution Type	ACAL: Change Bottle No./RB: Change Bottle No.	Reagent blank and calibration are performed when the system switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle has a unique bottle number. Bottles have the same reagent lot number.
	ACAL: Change Lot No./RB: Change Lot No.	Calibration and reagent blank are performed when the system switches to a reagent bottle with a new lot number during analysis. This occurs when all sequenced reagent bottles with the same lot number become empty during sample analysis.
	ACAL: Change Lot No./RB: Change Bottle No.	Calibration is performed when the system switches to a reagent bottle with a new lot number during analysis. This occurs when all sequenced reagent bottles with the same lot number become empty during sample analysis. Reagent blank is performed when the system switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle has a unique bottle number. All reagent bottles have the same reagent lot number.
	ACAL: None/ RB: Change Lot No.	Reagent Blank is performed when the system switches to a reagent bottle with a new lot number during analysis. Calibration is not performed.
	ACAL: None/ RB: Change Bottle No.	Reagent Blank is performed when the system switches to next sequence reagent bottle. Calibration is not performed.

NOTE

Automatic STAT calibration occurs during sample analysis. To perform calibration before QC and sample analysis, Advanced Calibration by Bottle No. or Lot No. is available. Refer to Calibration Specific Screen.

QC Parameters Menu

Program the controls used for QC analysis, and all specific QC parameters.

Quality control (QC) samples are used to confirm system performance and are a part of any diagnostic device.

Check the performance of the AU680 regularly by analyzing QC samples. Each laboratory should establish its own control frequency. Good laboratory procedure suggests QC samples be tested each time patient samples are tested and each time calibration is performed. If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should also establish guidelines to ensure corrective action if controls do not fall within the specified limits.

QC analysis can be performed in the green racks or the STAT table. When QC Barcode Operation is enabled, controls can be placed in any position in the green racks or STAT table.

When the AU680 is connected to a laboratory automation system, QC analysis must be performed with bar code labels from the STAT table.

⚠ CAUTION

Erroneous analysis data can cause erroneous diagnosis results. Always perform QC analysis at the same time as analysis of general patient samples to confirm that analysis is performed normally.

Controls Screen

Program a maximum of 100 controls required for specific tests. Control numbers 1 to 100 are programmed to a Type (Serum, Urine, Other-1, Other-2, or Whole Blood) by Beckman Coulter determined by laboratory requirements.

Select **Menu List > Parameters > QC Parameters > Controls**.

Figure 2.28 QC Parameters: Controls Screen

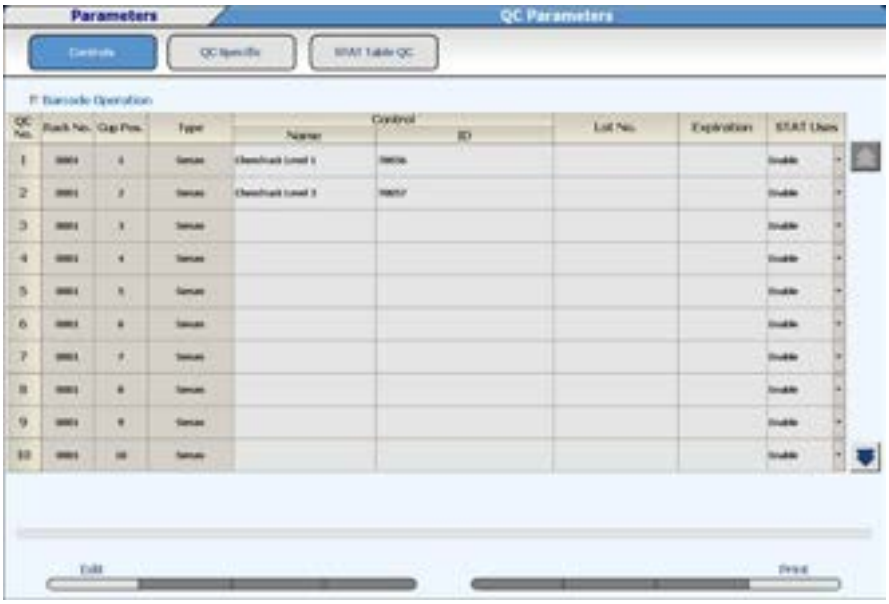


Table 2.26 Controls Screen Description

Item	Contents	Input Notes
Barcode Operation	Check or no check	If Barcode Operation is selected, control IDs are assigned to control material and controls can be placed in any position in the green rack or STAT table. If Barcode Operation is not selected, controls are assigned to positions in the green rack or STAT table.
Name	Control name	A maximum of 20 characters.
ID	Control ID (bar code)	A maximum of 26 alphanumeric characters for the control ID when Barcode Operation is selected.
Lot No.	Control lot number	A maximum of 15 alphanumeric characters.
Expiration	Control expiration date	Enter a date.
STAT Uses	Enable or Unable	Set to Enable to enable programming for the control on the STAT table.

QC Specific Screen

Program the specific control parameters for each test.

There are two quality control methods:

- Single check using the mean value and the standard deviation of the control
- Multi check with multiple rules including the tendencies of past results in the control

QC can be evaluated using Preset mode or Cumulative mode. In Preset mode, the QC mean, SD, and Range are entered in the Preset tab. In Cumulative mode, the QC mean, SD, and Range are calculated from QC run on the analyzer.

For more information, refer to Quality Control.

Check Tab

Select **Menu List > Parameters > QC Parameters > QC Specific > Check**.

Figure 2.29 QC Specific: Check Tab

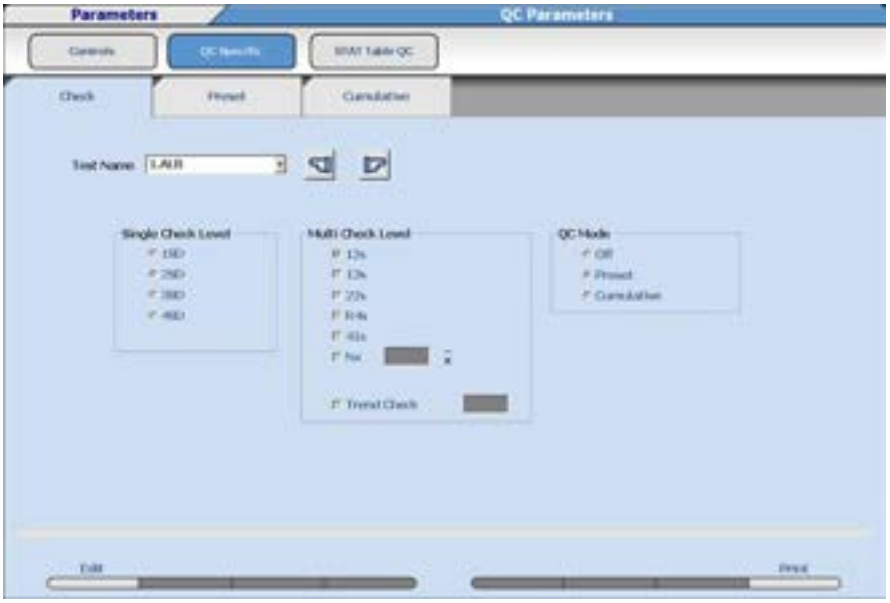


Table 2.27 Check Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Single Check Level	1SD, 2SD, 3SD, or 4SD	The standard deviation is checked as the control limit. Set the deviation level (1SD to 4SD). The flag is 1Q for any QC value that exceeds the SD level selected.

Table 2.27 Check Tab Description (Continued)

Item	Contents	Input Notes
Multi Check Level	Check 1_{2s}, 1_{3s}, 2_{2s}, R_{4s}, 4_{1s}, Nx, and/or Trend Check	• If 1_{2s} is checked and the control data on one side exceeds +/- 2SD, a 1Q flag is generated. • If 1_{3s} is checked and the control data on one side exceeds +/- 3SD, a 2Q flag is generated. • If 2_{2s} is checked and two consecutive control data exceeds +/- 2SD in the same direction, a 3Q flag is generated. • If R_{4s} is checked and consecutive high and low control data exceeds + 2SD and - 2SD, a 4Q flag is generated. • If 4_{1s} is checked and four consecutive control data exceeds +/- 1SD in any direction, a 5Q flag is generated. • If Nx is checked, program from 7 to 10 points to check if consecutive control data is above or below the mean value. A 6Q flag is generated. • If Trend Check is checked, program from 4 to 10 points to check for consecutively increasing or decreasing values. A 7Q flag is generated. When using Multi Check, the 1_{2s} must be checked to initiate the process in order for the following checks to be implemented when the 1_{2s} is exceeded.
QC Mode	Off, Preset, or Cumulative	• If Off is selected, a QC check is not performed and QC alarms and flags are not generated. • If Preset is selected, QC alarms and flags are generated from the values programmed in the Preset tab. • After QC has been run on the analyzer for a user defined number of QC samples, the QC mean, Standard deviation, and range can be calculated in the Cumulative tab. If Cumulative is checked, QC alarms and flags are generated from the calculated QC values obtained from the analyzer.

Preset Tab

When Preset mode is selected, known values must be entered for the mean, SD, and range. A maximum of 10 controls can be programmed for each test and sample type.

Select **Menu List > Parameters > QC Parameters > QC Specific > Preset**.

Figure 2.30 QC Specific: Preset Tab

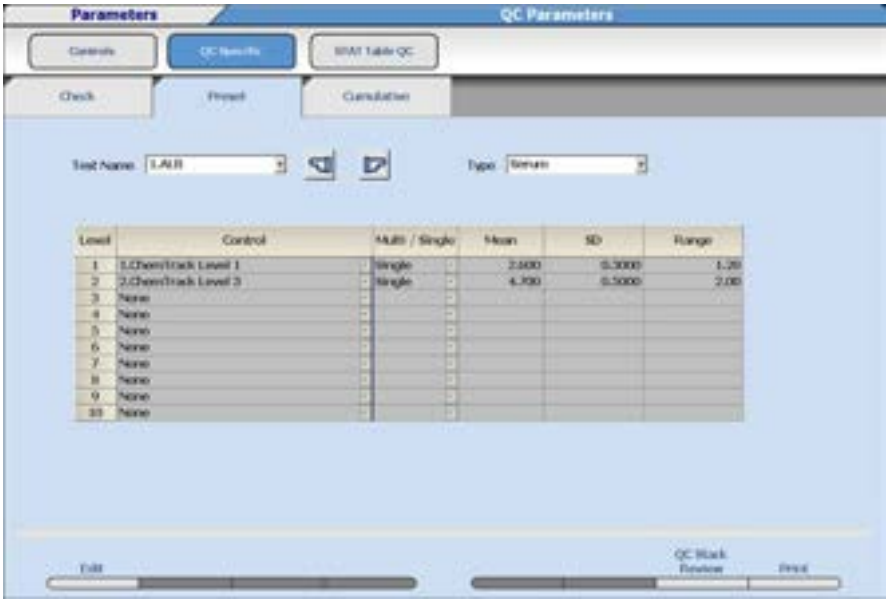
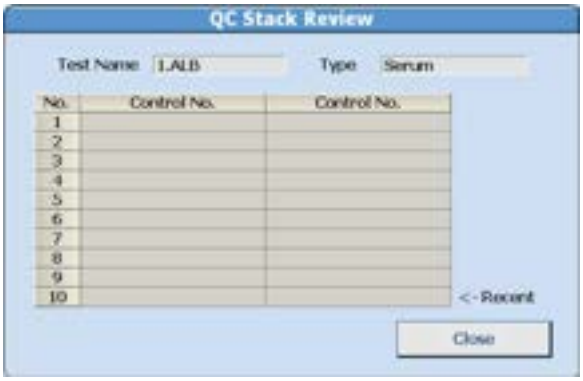


Table 2.28 Preset Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Control	Control material	Select the control material. The available QC materials are programmed in the Controls screen.
Multi/Single	Multi or Single	Program each Control to use Single Check or Multi Check rules. Two controls must be programmed to use Multi Check.
Mean	QC mean value	
SD	Standard deviation	Enter the value of one standard deviation.
Range	Range value	Enter the value of the range for acceptable QC.
QC Stack Review (F7)	Displays the last 10 QC results for the low and high control for the test.	QC data only displays if the test is programmed to Multi. Select **Close** to close the dialog.

Figure 2.31 QC Stack Review Dialog



NOTE

Only controls that are common to all tests in the calculation can be programmed for QC on calculated tests.

If two controls are programmed to Multi, it is possible to display the Twin Plot chart in **QC Monitor**.

Cumulative Tab

When QC Mode is set to Cumulative, the QC mean, standard deviation, and range can be calculated from QC data run on the analyzer.

Select **Menu List > Parameters > QC Parameters > QC Specific > Cumulative**.

Figure 2.32 QC Specific: Cumulative Tab

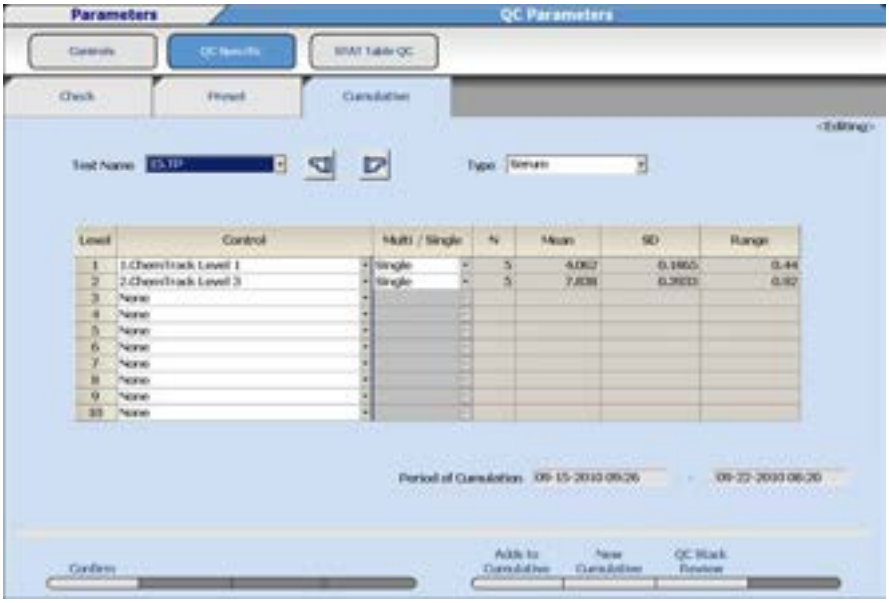


Table 2.29 Cumulative Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Control	Control material	Select the control material. The available QC materials are programmed in the Controls screen.
Multi/Single	Multi or Single	Program each Control to use Single Check or Multi Check rules. Two controls must be programmed to use Multi Check.
Period of Cumulation	Displays the Start Index and End Index selected for the calculation of QC statistics.	
Adds to Cumulative (F5)	Start Index and End Index to calculate QC statistics.	Adds QC data from the selected Start Index and End Index to any existing QC statistics, and calculates a new QC mean, SD, and range. When **OK** is selected, the number of QC data points (N), QC Mean, SD, and Range are calculated and displayed.
New Cumulative (F6)	Start Index and End Index to calculate QC statistics.	Calculates a new QC mean, SD, and range based on the Start Index and End Index. When **OK** is selected, the number of QC data points (N), QC Mean, SD, and Range are calculated and displayed.

Figure 2.33 New Cumulative Dialog and Adds to Cumulative Dialog

NOTE

Only controls that are common to all tests in the calculation can be programmed for QC on calculated tests.

STAT Table QC Screen

All required controls must be programmed for STAT table analysis when using Fixed Positions for controls.

- If QC barcode operation is in use, the controls can be placed in any of the Fixed Positions for controls.

- If QC barcode operation is not in use, the controls must be placed in the Fixed Position specifically programmed for each control.

For information on Fixed Positions, Variable Positions, and Free Positions, refer to Program STAT Table Parameters.

CAUTION

The inside of the STAT table compartment is refrigerated, but it is not intended for long-term storage of samples. Controls should be set on the STAT table only for the shortest time required.

For more information, refer to Controls Screen.

NOTE

Menu List > Parameters > QC Parameters > STAT Table QC > Position and QC Specific tabs cannot be programmed when using Free Positions or Variable Positions on the STAT table. These tabs are not available after selecting **Edit (F1)**.

Program Controls on the STAT Table

Select **Menu List > Parameters > QC Parameters > STAT Table QC > Position**.

Figure 2.34 STAT Table QC: Position Tab

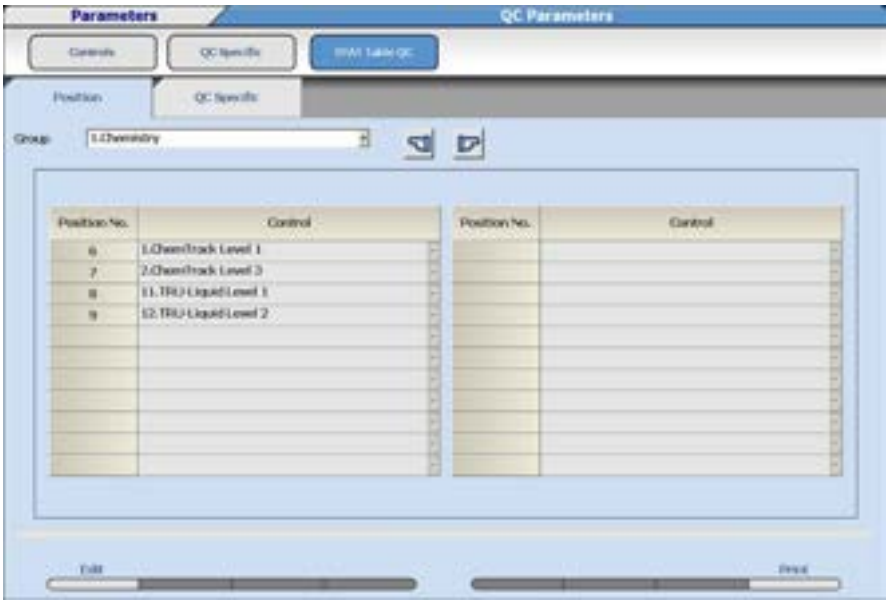


Table 2.30 Position Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **Group 1**, **2**, or **3** to program controls on the STAT table for the Group.

Table 2.30 Position Tab Description (Continued)

Item	Contents	Input Notes
Position No. (displays if QC Barcode Operation is No) or Number (displays if QC Barcode Operation is Yes)	Position 1 to 22	Displays the available control position numbers. Positions are assigned for controls in the Analysis mode screen. For programming information, refer to Program STAT Table Parameters.
	Sequential number	Displays the number of available control positions beginning with one. Positions are assigned for controls in the Analysis mode screen. Refer to Program STAT Table Parameters.
Control	Control name	Select the control in the Control column.

Program Specific Control Parameters on the STAT Table

Automatic STAT QC is available by programming **Test** or **Sample** in **Cyclic Type**, or **Yes** in **Execute after Calibration**.

Automatic STAT QC occurs during sample analysis after calibration, or a specified number of samples or tests are processed, and the necessary control(s) is available on the STAT table.

When automatic STAT QC is programmed, the amber STAT TABLE LED continuously blinks slowly during analysis.

Program **None** for all items in Cycle Type if cyclic automatic STAT QC is not required.

Program **No** for Execute after Calibration if automatic STAT QC after calibration is not required.

Select **Menu List > Parameters > QC Parameters > STAT Table QC > QC Specific**.

Figure 2.35 STAT Table QC: QC Specific Tab

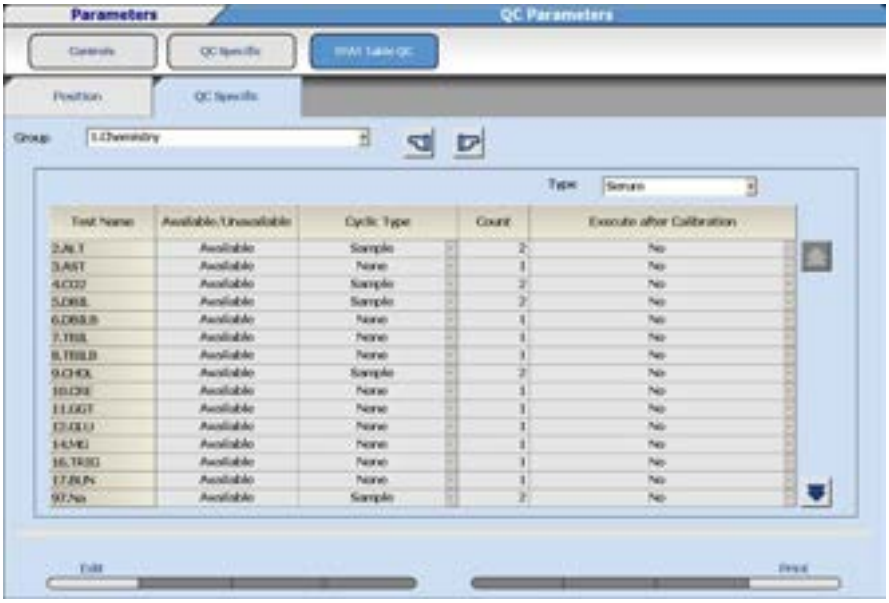


Table 2.31 QC Specific Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **Group 1**, **2**, or **3** to program controls on the STAT table for a Group.
Type	Serum, Urine, Other-1, or Other-2	In **Type** select the sample type.
Test Name	Test name	Displays the test names assigned to **Group**.
Available/Unavailable	Available or Unavailable	Displays Available if all the necessary controls are listed in the Position tab.
Cyclic Type	None	QC analysis is not performed automatically from the STAT table.
	Test	QC is performed automatically from the STAT table after analysis of the programmed number of tests (Count).
	Sample	QC is performed automatically from the STAT table after analysis of the programmed number of samples (Count).
Count	1 to 999	The test or sample number interval before QC is performed automatically from the STAT table.
Execute after Calibration	Yes or No	Select **Yes** to perform QC automatically from the STAT table after reagent blank or calibration.

Misc. Menu

Checked Tests Screen

Obtain a value with optional calculated tests using multiple tests and check if this value is within a range programmed in advance. If the check result is out of range, a T flag is added to the result.

For each sample type, a maximum of 10 calculations can be programmed.

Program the calculations for the tests to be checked.

Select **Menu List > Parameters > Misc. > Checked Tests**.

Figure 2.36 Misc.: Checked Tests Screen

Table 2.32 Checked Tests Screen Description

Item	Contents	Input Notes
Checked Test Name	Checked test name	The checked test name must be programmed in Check Name before it displays in **Checked Test Name**.
Check Name	Checked test name	Select **Check Name** to enable checked test programming. Enter a maximum of 8 characters for the checked test name.
Type	Serum, Urine, Other-1, or Other-2	
Test Name A, B, C, D, E	Test name	
Constant a, b, c, d	Value or Patient Inf.-1 to Patient Inf.-6	If Value is selected, enter a numerical value (maximum of 7 digits) in **Value**. If Patient Inf.-1 to Patient Inf.-6 is selected, a value entered in patient demographics in the order (requisition) is used for the constant.
Formula	Check calculation formula	Enter the formula with the characters +, -, *, /, (,), A, B, C, D, E, a, b, c, d using a maximum of 20 characters.
Set Decimal Places (F5)	0 to 4	Select the number of decimal places for the Check Range.
Check Range	Low and High limit for the check range	A T flag is generated if the Check Range is exceeded.

Figure 2.37 Set Decimal Places Dialog

Contamination Parameters Screen

Although the system has sufficient washing capability, cross contamination can occur in easily affected samples, or in analysis tests with high sensitivity. Extra washing conditions and avoidance parameters can be programmed to prevent such contamination.

⚠ CAUTION

When contamination prevention conditions are programmed, the analysis processing speed can decrease. Consult the Reagent Instruction for Use (IFU) or the reagent manufacturer.

Contamination Prevention Tab

Program reagent, mix bar, and cuvette contamination avoidance conditions for easily affected items.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Contamination Prevention**.

Figure 2.38 Contamination Parameters: Contamination Prevention Tab

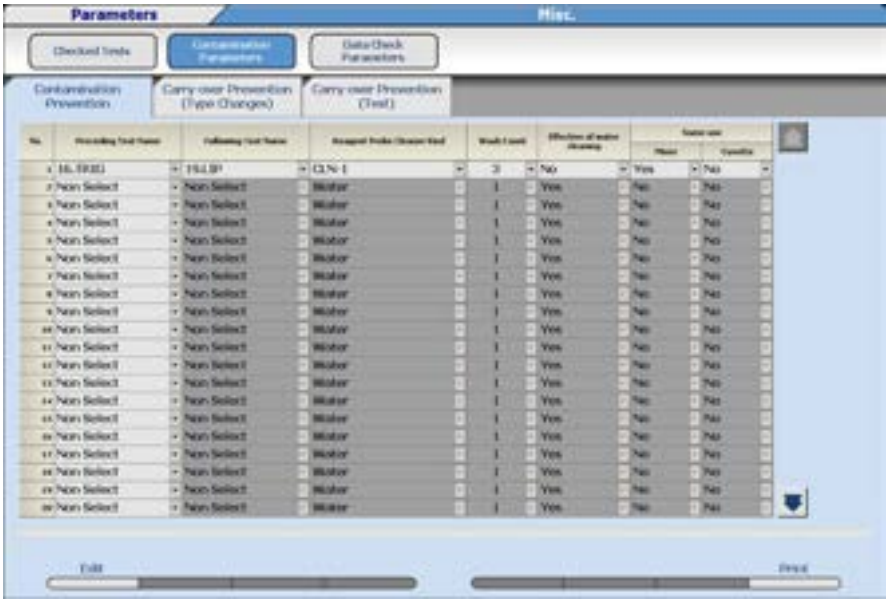


Table 2.33 Contamination Prevention Tab Description

Item	Contents	Description
Preceding Test Name	Test name	Select the test and type to perform extra washing before the test analysis. The cleaning solution (CLN-1, CLN-2), or All can also be selected for the preceding test.
Type	R1 or R2	
Following Test Name	Test name	Select the test and type, or All that is affected by the preceding test.
Type	R1 or R2	
Reagent Probe Cleaner Kind	Water, CLN-1 or CLN-2	The reagent probe is cleaned with water, CLN-1 (cleaning solution 1), or CLN-2 (cleaning solution 2). The required cleaning solution is placed on the analyzer by the R1 and R2 refrigerators. The R1 positions are 62. CLN-1 and 63. CLN-2. The R2 positions are 49. CLN-1 and 50. CLN-2.
Wash Count	1 to 5	Enter the quantity of times the reagent probe is washed in water or cleaning solution.
Effective of Water Cleaning	Yes or No	If the Effective of Water Cleaning is Yes, the normal rinsing of the reagent probe with deionized water between tests has the same cleaning effect as the programmed contamination avoidance cleaning. If the Wash Count is set to 5 for CLN-1, and 5 or more tests are run between the two affected tests, the additional cleaning with the CLN-1 solution is not required. If the Effective of Water Cleaning is No, cleaning 5 times in CLN-1 always occurs before the affected test, even if 5 or more tests were run between the two affected tests.
Mixer	Yes or No	If Yes is selected, the mix bar is not used for the Following Test immediately after the Preceding Test. If No is selected, the mix bar can be used for processing of the Following Test.
Cuvette	Yes, Yes (CLN-1), Yes (CLN-2) or No	If Yes is selected, the cuvette is skipped or used for a test other than the Following Test after the Preceding Test. If Yes (CLN-1) or Yes (CLN-2) is selected, the cuvette is washed with CLN-1 or CLN-2 after the Preceding Test or used for a test other than the Following Test after the Preceding Test. If No is selected, the cuvette can be used for processing the Following Test.

The example below shows the difference between when the Effective of water cleaning is programmed to **Yes** and **No**.

Other settings:

- Preceding Test Name: A
- Following Test Name: B

- Reagent Probe Cleaner Kind: CLN-1 or CLN-2
- Wash Count: 5

  In these settings, test sequence of two samples that require seven tests, A, B, C, D, E, F and G is as following. In this sequence, w is a cycle of cleaner washing.
- Effective of water cleaning is **Yes**: First sample: B, A, C, D, E, F, G Second sample: B, A, C, D, E, F, G
- Effective of water cleaning is **No**: First sample: B, A, C, D, E, F, G Second sample: A, C, D, E, F, G, w, w, w, w, w, B

Carry-over Prevention (Type Changes) Tab

Program extra cleaning for the sample probe between different sample types.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Carry-over Prevention (Type Changes)**.

Contact Beckman Coulter for detailed information about contamination parameters.

Figure 2.39 Contamination Parameters: Carry-over Prevention (Type Changes) Tab

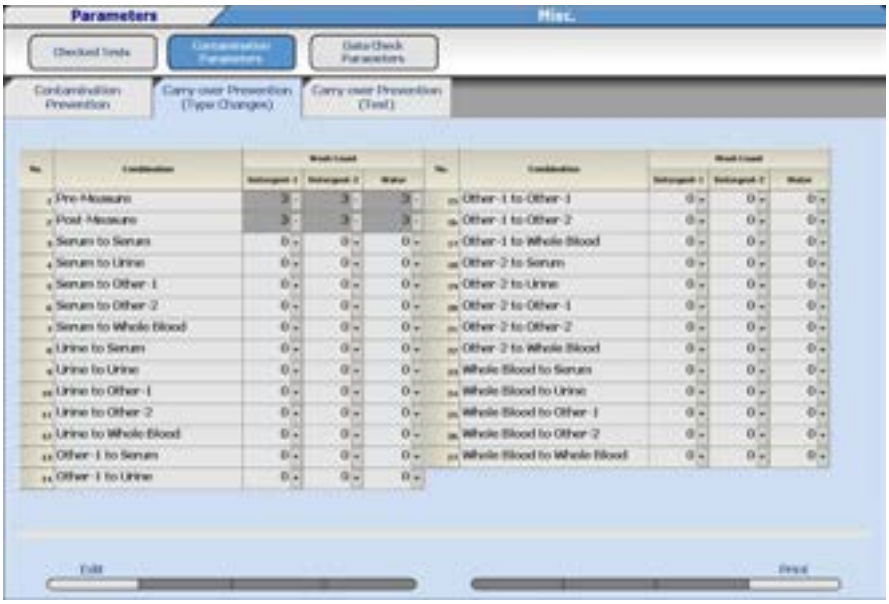


Table 2.34 Carry-over Prevention (Type Changes) Description

Item	Contents	Input Notes
Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the quantity of times the sample probe is cleaned in water, Detergent-1 or Detergent 2 when changing between sample types designated by the rack ID. Detergent-1 and Detergent-2 are cleaning solutions placed in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.

Carry-over Prevention (Test) Tab

Program extra sample probe washes before or after tests that are highly sensitive.

Program the washing count after analysis for tests affecting other tests. Program the washing count before analysis for tests easily affected by other tests.

Contact Beckman Coulter for more information about contamination parameters.

Select **Menu List > Parameters > Misc. > Contamination Parameters > Carry-over Prevention (Test)**.

Figure 2.40 Contamination Parameters: Carry-over Prevention (Test) Tab

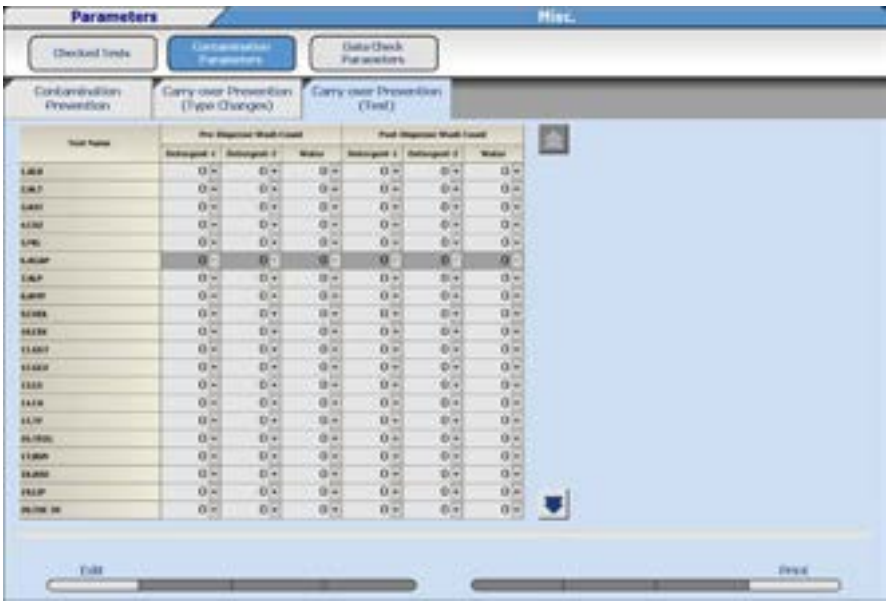


Table 2.35 Carry-over Prevention (Test) Tab Description

Item	Contents	Input Notes
Pre-Dispense Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the quantity of times the sample probe is cleaned in water, Detergent-1 or Detergent 2 before dispensing the test (Test Name). Detergent-1 and Detergent-2 are cleaning solutions placed in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.
Post-Dispense Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the quantity of times the sample probe is cleaned in water, Detergent-1 or Detergent 2 after dispensing the test (Test Name). Detergent-1 and Detergent-2 are cleaning solutions placed in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.

Data Check Parameters Screen

Program check points and decision limits to detect 1 of 4 different abnormal reaction types for prozone effects in an increasing turbidimetric test. Data check parameters are provided on the chemistry setting sheet, if necessary. For more information, contact Beckman Coulter.

1 Select **Menu List > Parameters > Misc. > Data Check Parameters**.

Figure 2.41 Misc.: Data Check Parameters Screen

Table 2.36 Data Check Parameters Screen Description

Item	Description
Check Point 1 to 3	Enter the photometric measuring point for judgment or the photometric measuring point for start of judgment.
Check Point Interval	Enter the point interval from the judgment start point for check. No input is possible for logic check 1.
Decision Value 1 to 3	Enter the OD to be used for judgment.
Limit Point 1, 2	Set judgment points other than check points. When the low concentration reaction and Prozone draw similar curves, this can be used to cancel low concentration.
Check Pattern (Only Logic Check 1)	Pattern 1: Judgment formulas 1 and 2 are applied. Pattern 2: Only judgment formula 1 is applied. Pattern 3: Only judgment formula 2 is applied. Pattern 4: Both judgment formulas 1 and 2 are not applied (a case where the center part is taken).

2 Select **Edit (F1)**.

3 Enter a check for one of the data check items 1 through 3 and program the data check tests. Multiple data checks can be checked.

4 When **Set Prozone Parameters (F5)** is selected, data calculation using a dedicated calibration type can be done. The Set Prozone Parameters dialog opens.

Figure 2.42 Set Prozone Parameters Dialog

This is a polygonal line of the 6MB formula type, and the concentration value for OD is set.

5 Select **Close** to close the Set Prozone Parameters dialog.

6 Confirm that the information is correct, and then select **Confirm (F1)**.

System Condition Menu

System parameter options affect system operations and software.

Analysis Mode Screen

Program the sample identification mode (sequential, Rack No., or barcode), auto repeat option, rack number limit for sample type, alarm sound, and STAT table options in the **Analysis mode** screen.

1 Select **Menu List > System > System Condition > Analysis mode**.

Figure 2.43 System Condition: Analysis Mode Screen

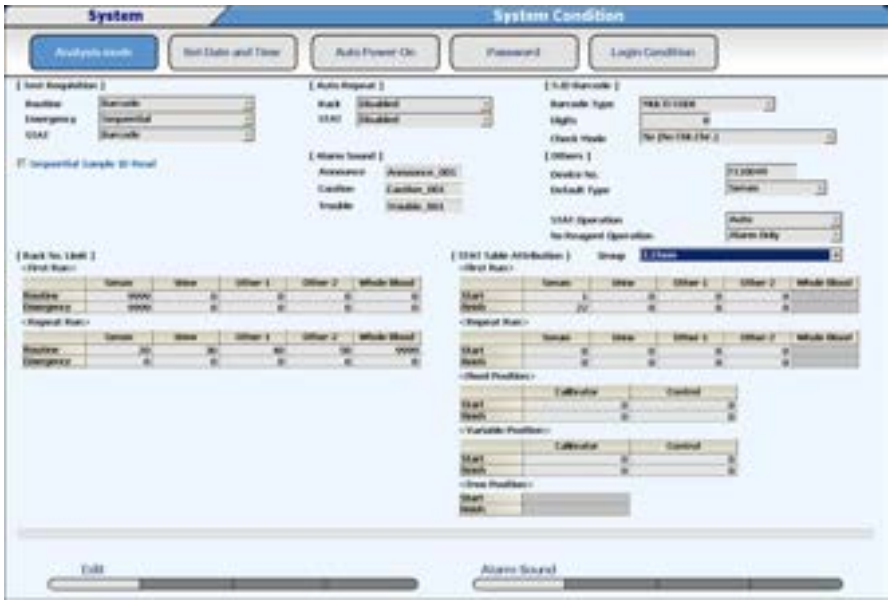


Table 2.37 Analysis Mode Screen Description

Option	Description
Test Requisition	Program the test requisition mode.
Auto Repeat	Program the auto repeat mode.
S.ID Barcode	Program the bar code type to be used for sample identification. Selection is possible from five types of bar codes. A MULTI CODE setting for use of multiple bar code types is also possible. Contact Beckman Coulter if MULTI CODE use is desired.
Alarm Sound	Program the alarm sound generated by the system. If multiple systems are in use, each system can be identified by a different alarm sound.
Others	Program other system conditions.
Rack No. Limit	Program the rack ID number limit for each sample type for the original and repeat run.
STAT Table Attribution	Program the STAT table positions for each sample type for the original and repeat run, and other STAT table options.

2 Select **Edit (F1)**.

3 Program the system parameters for each item in the table:

Table 2.38 Analysis Mode Description

Item	Contents	Input Notes
Test Requisition		
Routine[1] Emergency[3] STAT	Sequential Rack No. Barcode	— Sequential[2] - Performs an item inquiry in the order of sample tube detection. — Rack No.[3] - Performs an item inquiry in the order of rack ID number and sample position in the rack. Not available for STAT analysis. — Barcode - Performs an item inquiry according to the bar code ID attached to the sample cups.
Sequential Sample ID Read	Check box	— Checked - If Test Requisition mode is set to Sequential and the sample has a bar code label, the analyzer can read the bar code but does not link this number to the test requisition. The Bar code is stored as the sample ID in Sequential and Rack Number Mode.[2]
Auto Repeat		
Rack[3] STAT	Disabled Enabled	— Disabled - A repeat run list is generated after the initial run. The operator determines the samples to be repeated, and the repeat run is performed in the orange racks or STAT table repeat positions. — Enabled - The system automatically performs the repeat run using the repeat run parameters. Auto Repeat is disabled for STAT when Sequential is programmed for STAT in Test Requisition.
S. ID Barcode[4]		
Barcode Type[5]	Selection from 7 types	Refer to Sample Bar Code Specifications for available bar code types.
Digits[6]	0 to 26 digits	Including the check digit 0 means the number of digits is not specified.

Table 2.38 Analysis Mode Description (Continued)

Item	Contents	Input Notes
Check Mode[7]	No (No Chk. Chr.) No (With Chk. Chr.) Yes	— No (No Chk. Chr.) - Checking is not possible because bar codes without a check character are used. — No (With Chk. Chr.) - Bar codes with check characters are used, but checking is not done. — Yes - The check is performed.
Others		
Device No.	A 10-digit number	Beckman System ID (display only)
Default type	Serum, Urine, Other-1, Other-2, or Whole Blood	Select the default sample type to display on all menus from **Type**.
STAT Operation	Auto or Manual	Auto means a STAT table check is performed automatically when STAT analysis is started. Manual means a STAT table check must be performed by selecting **STAT Check (F3)** in **STAT Status** before STAT analysis can be started.
No Reagent Operation	Alarm Only or With Pause	— Alarm Only - Analysis continues except for the empty reagent. — With Pause - Analysis stops for all tests and the system shifts to *Pause* mode.

1. Barcode analysis must be used when the AU680 is connected to a laboratory automation system.
2. This option is only available on the STAT table when the AU680 is connected to a laboratory automation system.
3. This option is not available when the AU680 is connected to a laboratory automation system.
4. Programming is only available when the inquiry method is Barcode or if **Sequential Sample ID Read** is checked. The Check Character is not included as a component of the sample ID. It is not displayed or stored.
5. Refer to the Laboratory Automation System manual for available bar code types.
6. The bar code digits are 0 to 17 when the AU680 is connected to a laboratory automation system.
7. This option is not applicable when the bar code label is read on the laboratory automation system.

CAUTION

When the number of digits is set as 0 (no setting) for interleaved 2 of 5, a reading with missing digits can be interpreted as a correct reading. For example, when the digits at the edge of the label cannot be read because a label has been attached incorrectly, correct analysis is impossible. The same also applies when interleaved 2 of 5 is included in MULTI CODE.

CAUTION

Use of sequential analysis is not recommended for samples, as positive patient identification cannot be guaranteed.

Be aware that analysis without a sample ID can cause incorrect patient results.

4 Select **Alarm Sound (F5)**. The Alarm Sound dialog opens.

Figure 2.44 Alarm Sound Dialog

5 Select the alarm sound to be used for Announce (None or seven options), Caution (None or five options), and Trouble (None or six options).

If None is selected, no alarm sound is generated when the alarm event occurs.

NOTE

The selected alarm sound is played back when **Play** is selected. The alarm sound stops after a specified time or when **Stop**, **OK**, or **Cancel** is selected.

6 Select **OK**.

7 Confirm that the information is correct, and then select **Confirm (F1)**.

Program the Rack Number Limit

The system recognizes the sample type from the rack number bar code label. Set a rack ID number limit for each sample type. <First Run> routine samples correspond to a white rack, <First Run> emergency samples to a red rack, and <Repeat Run> samples to an orange rack.

NOTE

When the AU680 is connected to a laboratory automation system, or Sample Kind Mix is Enabled in System Maintenance, the rack ID number limit for sample type cannot be programmed.

It is possible to program the system to run serum, urine, other, and whole blood sample types in the same rack. Contact Beckman Coulter for more information.

1 Select **Menu List > System > System Condition > Analysis mode**.

Figure 2.45 System Condition: Analysis Mode Screen

2 Select **Edit (F1)**.

3 Enter the upper limit value for the rack ID number according to the following input value limitations for [Rack No. Limit].

Table 2.39 <First Run>

	Serum	Urine	Other-1	Other-2	Whole Blood
Routine	0 to 9999	0 or Serum column + 1 to 9999	0 or Urine column + 1 to 9999	0 or Other-1 column + 1 to 9999	0 or 9999 displays. Input is impossible.
Emergency					

Table 2.40 <Repeat Run>

	Serum	Urine	Other-1	Other-2	Whole Blood
Routine	0 to 9999	0 or Serum column + 1 to 9999	0 or Urine column + 1 to 9999	0 or Other-1 column + 1 to 9999	0 or Other-2 column +1 to 9999

Table 2.40 <Repeat Run> (Continued)

	Serum	Urine	Other-1	Other-2	Whole Blood
Emergency	0 or Routine Whole Blood column + 1 to 9999	0 or Emergency Serum column +1 to 9999	0 or Emergency Urine column +1 to 9999	0 or Emergency Other-1 column + 1 to 9999	0 or 9999 displays. Input is impossible.

The number of digits of the rack ID number is four or five digits according to the programming at installation. The standard is four digits. The explanations apply for four digits.

The corresponding racks are white racks for <First Run> routine samples, red racks for <First Run> emergency samples, and orange racks for <Repeat Run> routine and emergency samples.

The number entered for each sample type is the rack ID upper limit. Starting with the Serum column, then Urine, Other-1, Other-2, and finally Whole Blood, the number entered must be higher (up to 9999) or 0.

Sample types programmed to 0 cannot be analyzed.

Columns have 0 or 9999 assigned automatically.

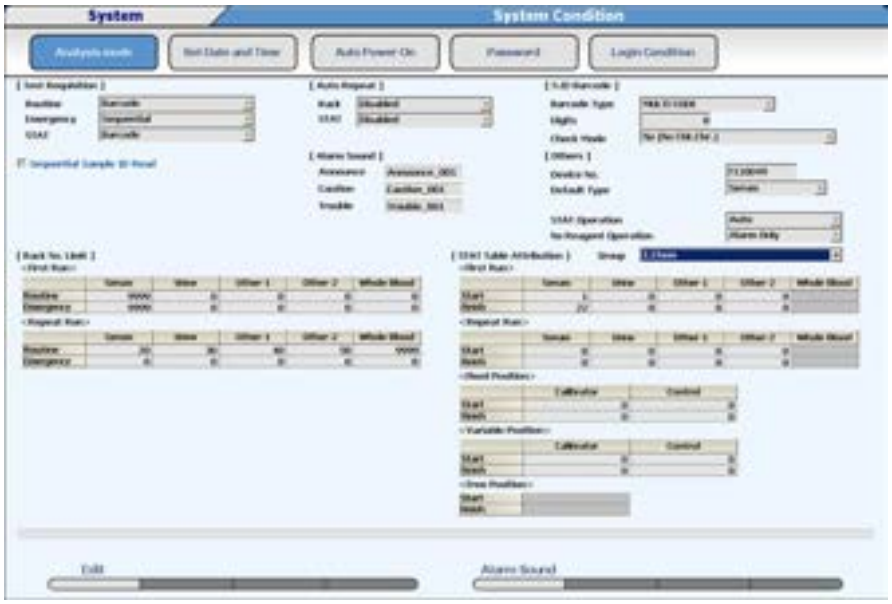
4 Confirm that the information is correct, and then select **Confirm (F1)**. If there is a discrepancy, the setting with the discrepancy is highlighted, and the display stays in edit mode.

Program STAT Table Parameters

Program the STAT table positions 1 to 22 for STAT samples, repeats, calibrators, or QC for each sample type.

1 Select **Menu List > System > System Condition > Analysis mode**.

Figure 2.46 System Condition: Analysis Mode Screen



2 Select **Edit (F1)**.

3 Program the system parameters for each item in the table below, and for each Group in use on the system.

There are 22 total positions on the STAT table. When programming <First Run>, <Repeat Run>, <Fixed Position>, <Variable Position>, and <Free Position>, the position numbers 1 to 22 cannot be duplicated or overlap. The Start number must always be less than the Finish number for all categories.

<Free Position> 1 to 22 can be ideal for programming the STAT table when the AU680 is connected to a laboratory automation system. If the laboratory automation system is not functioning, all sample types can be processed from the STAT table.

Table 2.41 Analysis Mode Description

Item	Contents	Input Notes
STAT Operation	Auto or Manual	Auto enables an automatic STAT table check when starting analysis on the STAT table. Manual requires the operator to initiate a STAT table check before starting analysis on the STAT table. A STAT table check detects sample cups and reads sample IDs for positions 1 to 22 on the STAT table.
Group	Group 1, 2, or 3	In **Group** select Group 1, 2, or 3.
<First Run> Start and Finish for Serum, Urine, Other-1 and Other-2	1 to 22	Program the Start and Finish position numbers for each sample type for priority STAT analysis. Program all positions (1 to 22) without overlapping numbers. The Start number must be less than the Finish number for each sample type. It is impossible to program Whole Blood for analysis on the STAT table.

Table 2.41 Analysis Mode Description (Continued)

Item	Contents	Input Notes
<Repeat Run> Start and Finish for Serum, Urine, Other-1 and Other-2	1 to 22	Program the Start and Finish position numbers for each sample type for repeat priority STAT analysis. Program all positions (1 to 22) without overlapping numbers. The Start number must be less than the Finish number for each sample type. It is impossible to program Whole Blood for analysis on the STAT table. <Repeat Run> positions are only required for STAT Manual Repeat. If STAT Auto Repeat is enabled, the STAT sample automatically repeats in the <First Run> position.
<Fixed Position> Start and Finish for Calibrator and Control	1 to 22	Program the Start and Finish position numbers for calibrators and controls. For information on programming the calibrators to the calibrator positions, and calibration specific parameters, refer to STAT Table Calibration Screen. For information on programming the controls to control positions, and QC specific parameters, refer to STAT Table QC Screen.
<Variable Position> Start and Finish for Calibrator and Control	1 to 22	Program the Start and Finish position numbers for calibrators and controls. Calibrators and control Barcode Operation are not enabled. The calibrator or control position is determined during the calibrator and QC order (requisition) process. The calibrator and control are placed in a <Variable Position>. It is not necessary to have a <Fixed Position> for calibrator or control.
<Free Position> Start and Finish	1 to 22	Priority STAT samples, repeats, calibrators, and controls can be processed in any <Free Position>. Sample Kind Mix must be Enabled in System Maintenance by Beckman Coulter. When Enabled, all sample types can be run in any position on the STAT table. If Disabled, calibration and QC are performed, but samples are not processed from <Free Position> on the STAT table. Calibrator and Control Barcode Operation must be enabled to process calibrators or controls in the <Free Position>.

4 Confirm that the information is correct, and then select **Confirm (F1)**.

Set Date and Time Screen

The system time is the current date and time and is displayed on the top right corner of the main button bar. The Current Date and Time are updated for daylight savings time depending on regional settings.

1 Select **Menu List > System > System Condition > Set Date and Time**.

Figure 2.47 System Condition: Set Date and Time Screen

1. Current Date and Time

2 Select **Edit (F1)**.

3 Set the current date from **Date**. Set the current time as a 24-hour display from **Time**.

4 Confirm that the information is correct, and then select **Confirm (F1)**. The system time is updated.

Auto Power On Screen

The lamp requires approximately 20 minutes to warm up after power ON before analysis can be started.

The system can be programmed to turn ON automatically at a specified time for each day of the week.

CAUTION

The automatic ON option does not open and close the main water valve, so it must be left open. Follow laboratory Standard Operating Procedures for inspecting the deionized water system and main water valve.

1 Select **Menu List > System > System Condition > Auto Power On**.

Figure 2.48 System Condition: Auto Power On Screen

2 Select **Edit (F1)**.

3 Select the desired day to start the Auto Power On function.

4 Set the hours and minutes.

5 To perform Auto Preparation, select **Auto Preparation**.

NOTE

The ability to perform Auto Preparation is enabled for each day of the week in System Maintenance by Beckman Coulter. The three auto preparation options are:

— W1
— Photocal
— W1 + Photocal

When System Maintenance is enabled, select the day of the week to perform the Auto Preparation.

6 Repeat steps 3 to 5 for each day to be set.

7 Confirm that the information is correct, and then select **Confirm (F1)**.

Login Condition and Password Screens

The system can be programmed with user names and passwords. The Log Out button on the main button bar is used to log in or out for each operator, and this information is then registered in the system.

Each user name is assigned to an access level. Access levels are assigned to menus, submenus, and functions such as Parameters Edit or QC Edit.

You can program a maximum of 30 user names with passwords, change user names, passwords, and access level, and delete users. For detailed information, refer to Program a New User Name and Password.

Select **Password** to change the password of the user currently logged in to the system.

Program the Access Level

Access levels can be programmed from 1 to 10 for each user name. The initial access level is 10, so all users assigned to 1 through 10 have access to menus. The most secure menu access level is 1, as only users assigned as a 1 have access. A user assigned to a 5 for example, has access to menus assigned from 5 to 10. Confirm that a user is programmed to have full access to all menus. For more information, refer to Program a New User Name and Password.

1 Select **Menu List > System > System Condition > Login Condition > Access Level**.

Figure 2.49 Login Condition: Access Level Tab

2 Select **Edit (F1)**.

3 Program the menu level within the range from 1 to 10.

NOTE

Set the level for the menu to the same or higher number than the number for submenu.

4 Repeat step 3 for all menus, submenus, and function levels.

5 Select **Confirm (F1)**. The Confirmation dialog opens.

NOTE

If there is any conflict in access levels between the menu and a submenu, an alarm dialog opens. Select **Cancel** to resolve the conflict, or **OK** to leave it unresolved.

6 Select **OK** to save the settings.

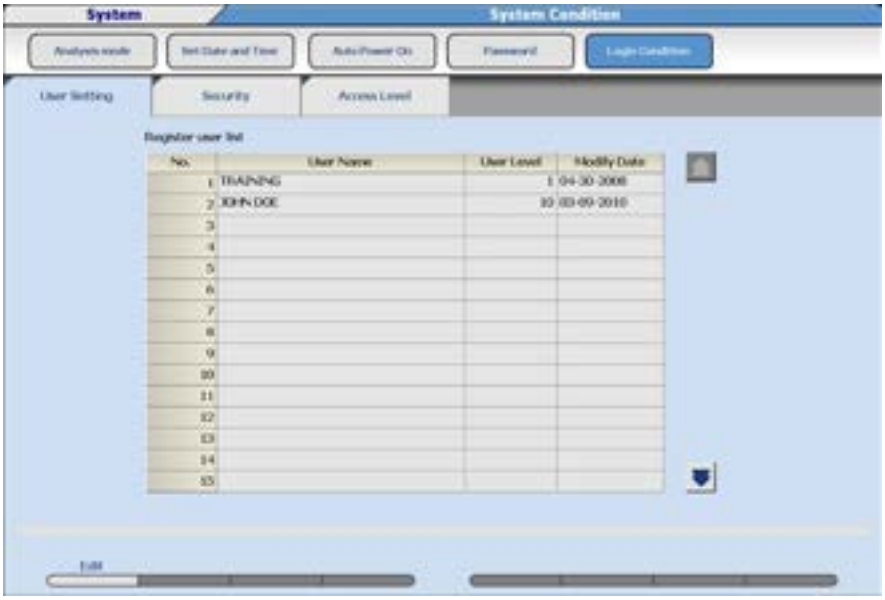
CAUTION

A submenu cannot be programmed with a higher number than the menu.

Program a New User Name and Password

1 Select **Menu List > System > System Condition > Login Condition > User Setting**.

Figure 2.50 Login Condition: User Setting Tab



2 Select **Edit (F1)**.

3 Select an available No. (from 1 to 30).

4 Select **Addition of User (F2)**. The Addition of User dialog opens.

Figure 2.51 Addition of User Dialog

5 Enter the **User Name**. Upper and lower case characters can be used for up to 20 characters.

6 Enter the new user's password in **Password**. Upper and lower case characters can be used for up to 20 characters. Use of a password is optional. If a password is not entered, the user name entered for login has access to the assigned user level.

7 For confirmation, re-enter the password entered in step 6 in **Confirm**.

8 If it is necessary to change the user access level, select 1 to 10 in the User Level column. A smaller number means a higher level of access to menus and functions.

9 Select **OK**.

10 Repeat steps 3 to 9 for each user.

11 Select **Confirm (F1)**. The Confirmation dialog opens.

12 Select **OK** to save the settings.

NOTE

Functions and menus that are not accessible mean that the user's User Level does not allow them to access these items. If the user needs access to these items, ask an administrator to change the user's User Level. For more information, refer to Program the Access Level.

Change the User Name Password or User Level

1 Select **Edit (F1)**.

2 From the Register user list, select the user name to be changed.

3 Select **Modify (F3)**. The Modify dialog opens.

Figure 2.52 Modify Dialog

4 Change the **User Name** if necessary.

5 Select **Change** to change the password if necessary.

6 Enter the **Current Password**.

7 Enter the **New Password**.

8 For confirmation, reenter the password entered in step 7 in **Confirm**.

9 If it is necessary to change the user access level, select 1 to 10 in the User Level column. A smaller number means a higher level of access to menus and functions.

10 Select **OK**.

11 Select **Confirm (F1)**. The Confirmation dialog opens.

12 Select **OK** to save the settings.

NOTE

To change the password for the user currently logged in the system, select **System Condition > Password**.

Delete Users

1 Select **Edit (F1)**.

2 Select the user name to be deleted and select **Delete (F4)**. The delete message appears.

3 Select **OK**. The user name is deleted.

4 Select **Confirm (F1)**. The Confirmation dialog opens.

5 Select **OK**. The user name is deleted.

Security Settings

Security options include programming a password expiration date, an auto lock of the computer, and an auto login feature.

1 Select **Menu List > System > System Condition > Login Condition > Security**.

Figure 2.53 Login Condition: Security Tab

2 Select **Edit (F1)**.

3 To set an expiration date for a password, select **Enable** next to Password Expiration Date. Enter the number of days that the password is effective before it has to be changed.

A number between 1 and 60 days can be set as an expiration date for a password.

4 To auto lock the screen, select **Enable** next to Auto Lock. Select a time from 5 to 60 minutes before the auto lock is activated from **Wait time**.

5 To enable the auto login function without inputting a user name and password at system startup, select **Enable** next to Auto Login. Select the user name to set up for auto login from **Auto Login User**.

6 Select **Confirm (F1)**. The Confirmation dialog opens.

7 Select **OK** to save the settings.

NOTE

The password expiration date is effective for all user names.

NOTE

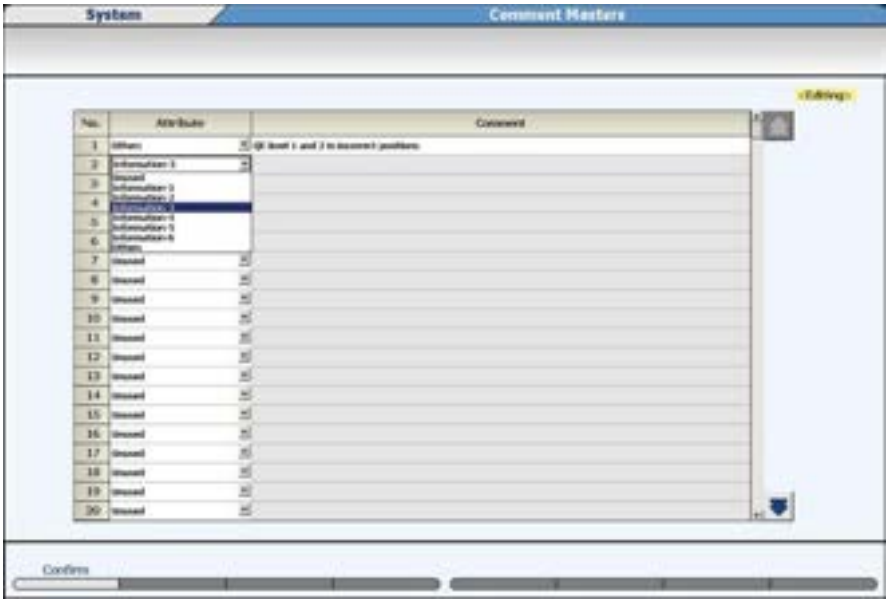
Auto Login cannot be used when Auto Lock is Enabled.

Comment Masters Menu

Program a list of standard comments that can be included easily with a Comment Master button, instead of re-entering the comment manually. Up to 240 comments can be programmed.

1 Select **Menu List > System > Comment Masters**.

Figure 2.54 System: Comment Masters Screen



2 Select **Edit (F1)**.

3 In **Attribute** select the comment attribute.

- Unused -The comment is not used (no comment).
- Information 1 to 6 - The comment can be selected in the 1 to 6 demographic fields in **Rack Requisition > Demographics** and **Home > STAT Status > Sample > Demographics**.
- Others - The comment can be selected in **Start Condition** in **Operator Name**, **Rack Requisition > Demographics** in **Comment**, **Calibration Monitor**, **QC Monitor**, and **Calibration Verification**.

4 Enter the Comment.

- Unused - Cannot be edited. If the attribute of a comment that has already been entered was changed to Unused, the entered comment is retained.
- Information 1 to 6 - Up to 20 characters can be entered.
- Others - Up to 50 characters can be entered.

NOTE

Program the 1 to 6 patient demographic titles in **<Patient Information>** in **Menu List > System > Format > Requisition Format**. The patient demographic titles display in **Home > Rack Requisition Sample > Demographics** and **Home > STAT Status > Sample > Demographics**. Refer to Format Menu.

5 Confirm that the information is correct, and then select **Confirm (F1)**.

User Menu

The User Menu function allows the selection of up to 16 menus most frequently used by the operator. Operator-defined menu names can be programmed. Menus selected from the **User Menu** button have direct access to the menu to save time.

The system displays the original menu name below the main button bar even when you access menus using the **User Menu** button.

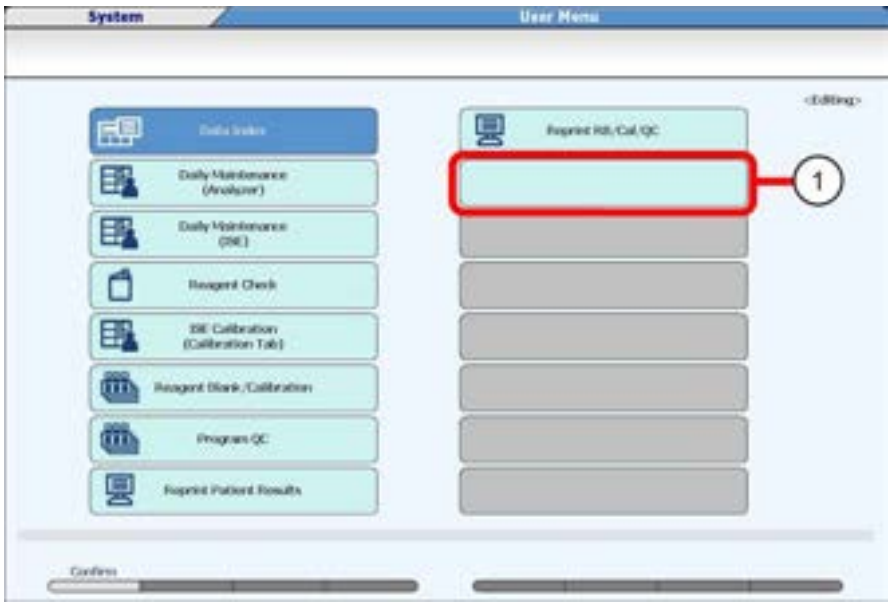
Edit the User Menu

1 Select **Menu List > System > User Menu**.

2 Select **Edit (F1)**.

The system changes the next available menu from a gray box to a blue button.

Figure 2.55 User Menu Screen



1. Blue button

3 Select the blue button.

Figure 2.56 User Menu Entry Dialog

4 In **Select Screen**, select the menu to place in the User Menu list.

5 Select **Decide**.

6 In **Display Data**, enter the operator-defined menu name. You can enter up to 28 characters on each line.

7 Select **Entry**.

8 Confirm that the information is correct, and then select **Confirm (F1)**.

Delete a Menu

To remove a menu from the **User Menu**:

1 Select **Menu List > System > User Menu**.

2 Select **Edit (F1)**.

3 Select the Menu to be deleted. The User Menu Entry dialog opens.

4 Select **Delete**. The specified menu is deleted.

5 Confirm that the information is correct, and then select **Confirm (F1)**.

Online Menu

Set the I/O (input/output) conditions for online connection of this system, a clinical laboratory information system or a Remisol/DataWizard middleware solution. Online parameters are typically programmed by Beckman Coulter.

Two methods to connect online:

- RS232C
- TCP/IP

RS232C is the default.

For changing methods, contact Beckman Coulter. This section describes how to configure each connection.

Program Online Parameters with RS232C Connection

Set Up Tab for RS232C

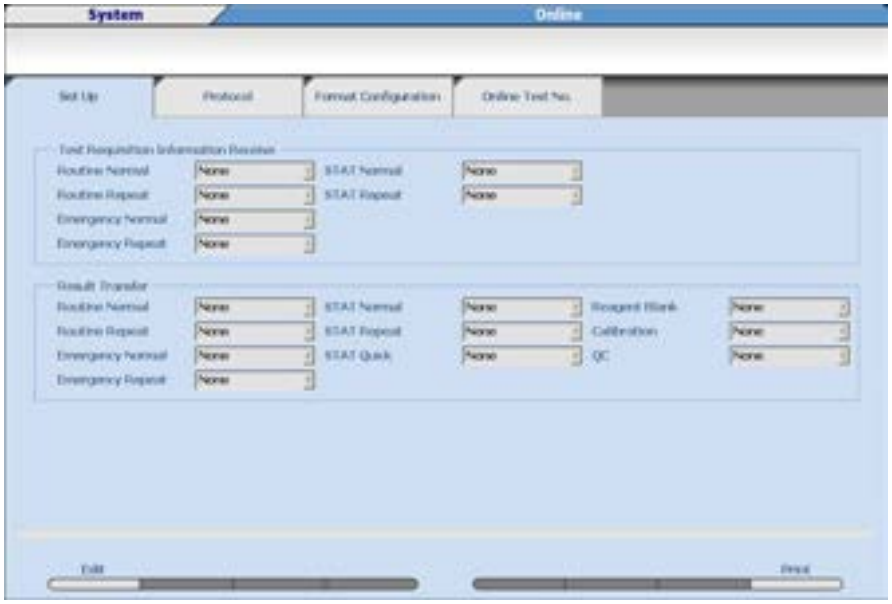
The communication method can be selected from the following three methods.

- Realtime - Test order (requisition) inquiries and analysis result output are performed during analysis.
- Batch - Test order (requisition) inquiries and analysis result output are performed by operator intervention.
- None - No online input/output is made.

---

1 Select **Menu List > System > Online > Set Up**.

Figure 2.57 Online: Set Up Tab



NOTE

— Test Requisition Information Receive: Program the test order (requisition) inquiry mode. Three inquiry modes are available for routine, emergency, repeat, and STAT:

  — Realtime
  — Batch
  — None (Default)

— Result Transfer - Program the output method for analysis results. Three output options are available for routine, emergency, repeat, STAT, reagent blank, calibration, and QC:

  — Realtime
  — Batch
  — None (Default)

When the AU680 is connected to a laboratory automation system, the setting for Routine Repeat, Emergency Normal, and Emergency Repeat are impossible.

2 Select **Edit (F1)**.

3 Select the communication method for each sample kind.

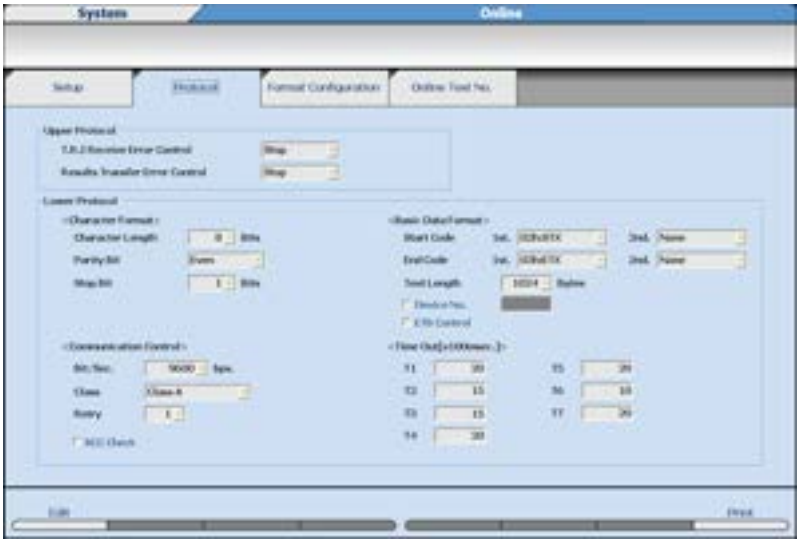
4 Confirm that the information is correct, and then select **Confirm (F1)**.

Protocol Tab for RS232C

The online communication protocol can be assigned and set.

1 Select **Menu List > System > Online > Protocol**.

Figure 2.58 Online: Protocol Tab



2 Select **Edit (F1)**.

3 Program the required parameters.

4 Confirm that the information is correct, and then select **Confirm (F1)**.

NOTE

Online parameters are typically programmed by Beckman Coulter.

Table 2.42 Protocol Tab Description

Setting	Range	Initial Value
Upper Protocol		

Table 2.42 Protocol Tab Description (Continued)

Setting	Range	Initial Value
T.R.I Receive Error Control	Stop/Continue — Stop - When a communication error occurs, there is no more communication after the sample with the communication error. — Continue - Even when a communication error occurs, T.R.I. is executed for the next sample.	Stop
Results Transfer Error Control	Stop/Continue — Stop - When a communication error occurs, there is no more communication after the sample with the communication error. — Continue - Even when a communication error occurs, T.R.I. is executed for the next sample.	Stop
Lower Protocol		
<Character Format>		
Character Length	7/8	7
Parity Bit	None/Even/Odd	None
Stop Bit	1/2	1
<Basic Data Format>		
Start Code (1st.)	01h:SOH to 1Fh:US	02h:STX
Start Code (2nd.)	None / 01h:SOH to 1Fh:US	None
End Code (1st.)	01h:SOH to 1Fh:US	03h:ETX
End Code (2nd.)	None/01h:SOH to 1Fh:US	None
Text Length	256/512/1024	1024
Device No.	Unchecked/Checked	Unchecked
Device No. (checked)	00 to 99	00
ETB Control	Unchecked / Checked	Unchecked
<Communication Control>		

Table 2.42 Protocol Tab Description (Continued)

Setting	Range	Initial Value
Bit/Sec.	4800/9600	9600
Class	Class A (No ACK/NACK) Class B (With ACK/NACK)	Class A
Retry	0 to 3	1
BCC Check	Unchecked/Checked	Unchecked
<Time Out [x 100msec.]>		
T1	1 to 99 msec.	20
T2	1 to 99 msec.	15
T3	1 to 99 msec.	15
T4	1 to 99 msec.	20
T5	1 to 99 msec.	20
T6	1 to 99 msec.	10
T7	1 to 99 msec.	20

NOTE

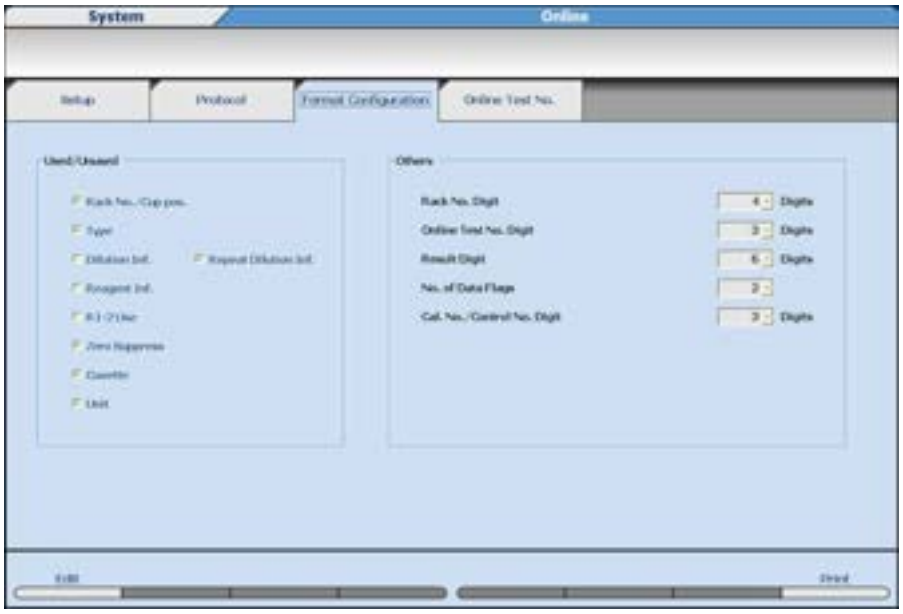
Program the protocol after confirmation with the system administrator of the laboratory information system. Correct communication may not be possible if there is a discrepancy with the settings on a laboratory information system.

Format Configuration Tab for RS232C

Program the additional information and digit number of data used for online communication.

1 Select **Menu List > System > Online > Format Configuration**.

Figure 2.59 Online: Format Configuration Tab



— Used/Unused - Program the information to be added to online communication messages. Selected items are sent through online communication.
— Others:

  — Rack No. Digit: Four or five digits
  — Online Test No. Digit: Program the number of digits (two or three) for the test No. programmed in Online Test No.
  — Result Digit: Program the number of digits (six or nine) for the data to be added to the message.
  — No. of Data Flags: Program the number of the data flags (two or four) to be added to the message.
  — Cal. No./Control No. Digit: Two or three digits

⚠ CAUTION

On the laboratory information system, the system administrator must set the data format after confirmation. If there is a discrepancy with the settings, it can affect communications with the laboratory information system.

2 Select **Edit (F1)**.

3 Select the **Used/Unused** items to be used for online communication.

4 Select the digits for each item from **Others**.

5 Confirm that the information is correct, and then select **Confirm (F1)**.

Online Test No. Tab for RS232C

Assign each test name to an online test number for online communication.

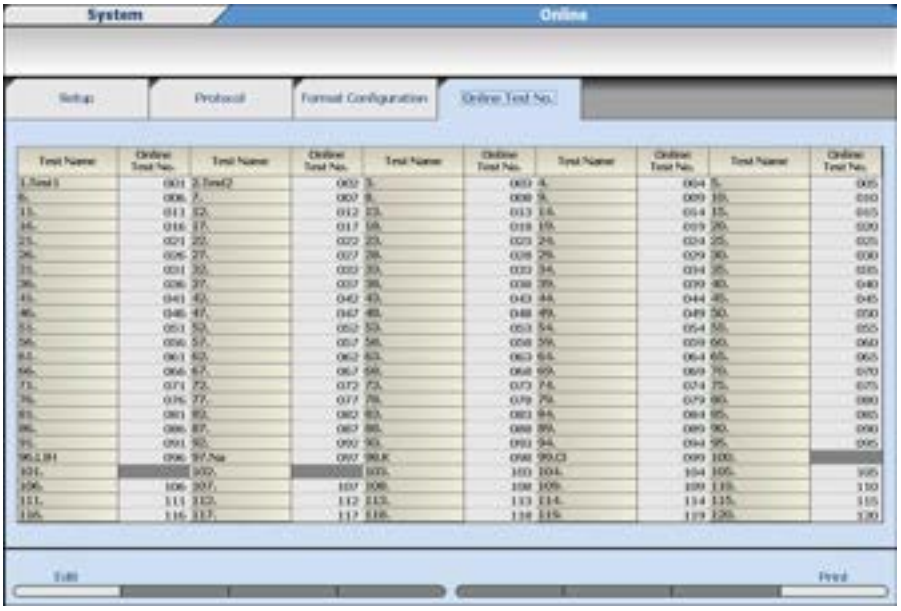
NOTE

Total and direct bilirubin are programmed as sample blank tests. For more information, refer to Test Name Screen.

For the blank test in sample blank tests, it is impossible to program an Online Test No. because the blank test result is only used for the calculation and is not a reported result.

1 Select **Menu List > System > Online > Online Test No**.

Figure 2.60 Online: Online Test No. Tab



2 Select **Edit (F1)**.

3 Move the cursor to the test name to be programmed.

4 Enter the **Online Test No.**. The combination of the online test number and test must coincide with the laboratory information system. Set the number as a blank when online communication is not required.

NOTE

When the test number of the laboratory information system and the online test number differ, the data may not be transmitted correctly.

5 Repeat steps 3 to 4 for each test to be programmed.

6 Confirm that the information is correct, and then select **Confirm (F1)**.

7 When numbers are duplicated, the Parameter Error(s) dialog displays. Select **Cancel** and correct.

Program Online Parameters with TCP/IP Connection

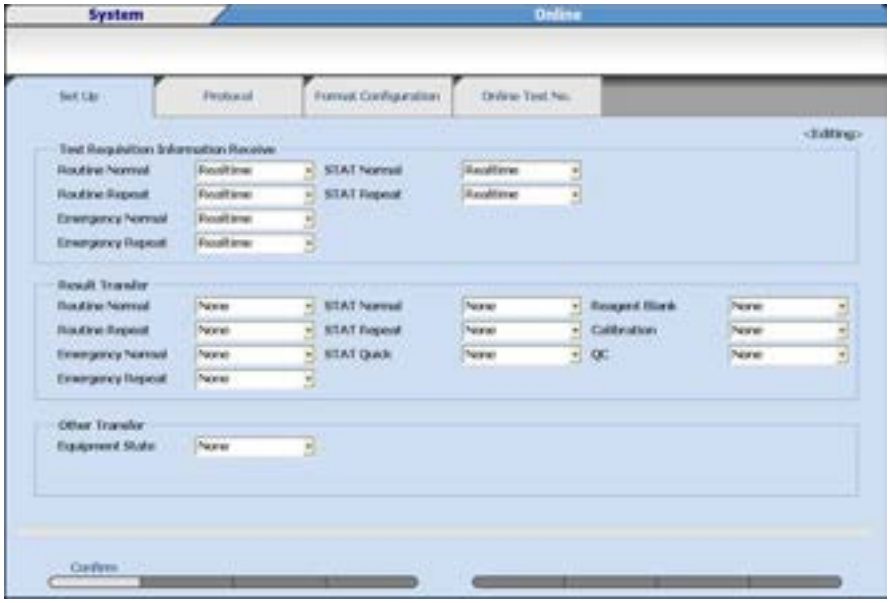
Set up Tab for TCP/IP

The communication method can be selected from the following four methods:

- Realtime - Test order (requisition) inquiries and analysis result transfers are performed realtime during analysis.
- HOST Direction - The laboratory information system sends test order (requisition) information to the AU680 computer, and the AU680 computer saves the information (without an inquiry process from the AU680 computer) during analysis and other modes.
- Batch - Analysis result output are performed by the operator.
- None - No online input or output is made.

1 Select **Menu List > System > Online > Set Up**.

Figure 2.61 Online: Set Up Tab



— Test Requisition Information Receive - Program the test order (requisition) inquiry mode. Three inquiry modes are available for routine, emergency, repeat, and STAT:

  — Realtime
  — Host Direction
  — None (default)

— Result Transfer - Program the output method for analysis results. Three output options are available for routine, emergency, repeat, STAT, reagent blank, calibration, and QC:

— Realtime
— Batch
— None (default)

— Other Transfer - Program the system for output to Host. Program Equipment Status to Enable when the test order (requisition) is received with Host Direction.

— Enable
— None (default)

2 Select **Edit (F1)**.

3 Select the communication method for each sample kind.

4 Confirm that the information is correct, and then select **Confirm (F1)**.

Protocol Tab for TCP/IP

The protocol for online communication can be programmed.

Setting items and setting ranges are shown below.

1 Select **Menu List > System > Online > Protocol**.

Figure 2.62 Online: Protocol Tab

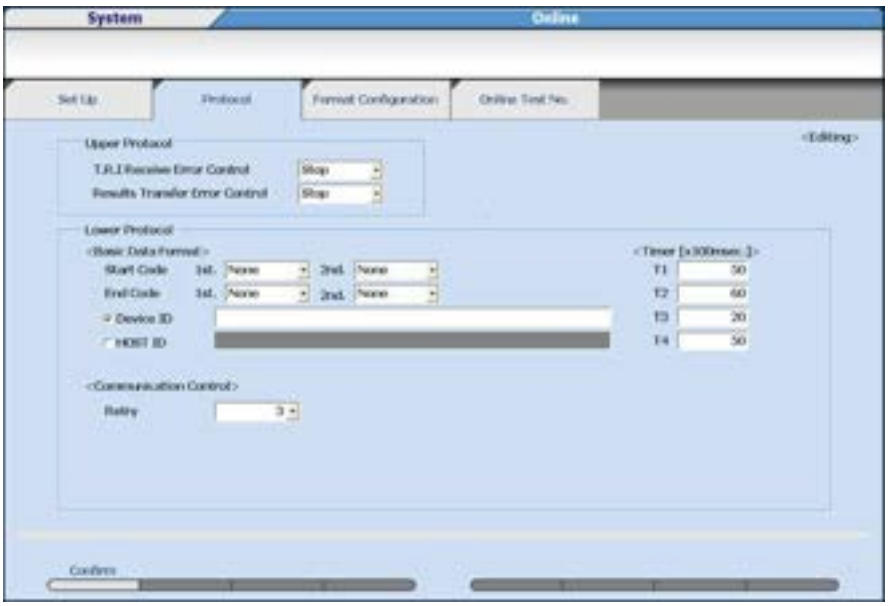


Table 2.43 Protocol Tab Description

Setting Item	Setting Range	Default
T.R.I Receive Error Control	Stop/Continue — Stop - When a communication error occurs on a sample, communication stops for any remaining samples. — Continue - When a communication error occurs on a sample, communication continues with the next sample.	Stop
Results Transfer Error Control	Stop/Continue — Stop - When a communication error occurs on a sample, communication stops for any remaining samples. — Continue - When a communication error occurs on a sample, communication continues with the next sample.	Stop
Start Code (1st.)	None / 01h to 1Fh	None
Start Code (2nd.)	None / 01h to 1Fh	None
End Code (1st.)	None / 01h to 1Fh	None
End Code (2nd.)	None / 01h to 1Fh	None
Device No. used/unused	Unchecked / Checked	Unchecked
Device No.	32 characters	-
HOST ID used/unused	Unchecked / Checked	Unchecked
HOST ID	32 characters	-
<Time Out [×100msec.]> T1	00 to 99 msec.	50
<Time Out [×100msec.]> T2	00 to 99 msec.	60
<Time Out [×100msec.]> T3	00 to 99 msec.	20
<Time Out [×100msec.]> T4	00 to 99 msec.	50
Retry	0 to 3	3

2 Select **Edit (F1)**.

3 Program the parameters.

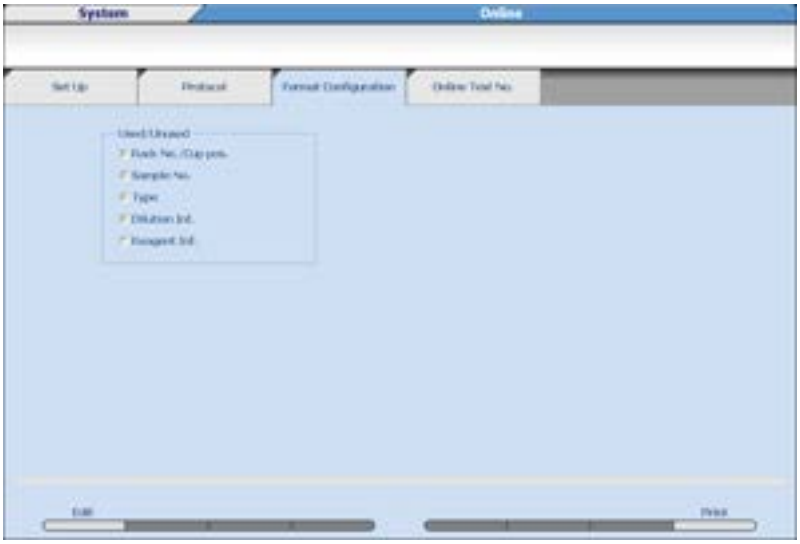
4 Confirm that the information is correct, and then select **Confirm (F1)**.

Format Configuration Tab for TCP/IP

Program the additional information to be used for online communications.

1 Select **Menu List > System > Online > Format Configuration**.

Figure 2.63 Online: Format Configuration Tab



CAUTION

On the laboratory information system, the system administrator must set the data format after confirmation.

If there is a discrepancy with the settings, it may affect communications with the laboratory information system.

NOTE

Used/Unused: Program the information to be added to the online communication messages. Selected items are sent through online communication.

2 Select **Edit (F1)**.

3 Select the **Used/Unused** items to be used for online communication.

4 Confirm that the information is correct, and then select **Confirm (F1)**.

Online Test No. Tab for TCP/IP

Assign each test name to an online test number for online communication.

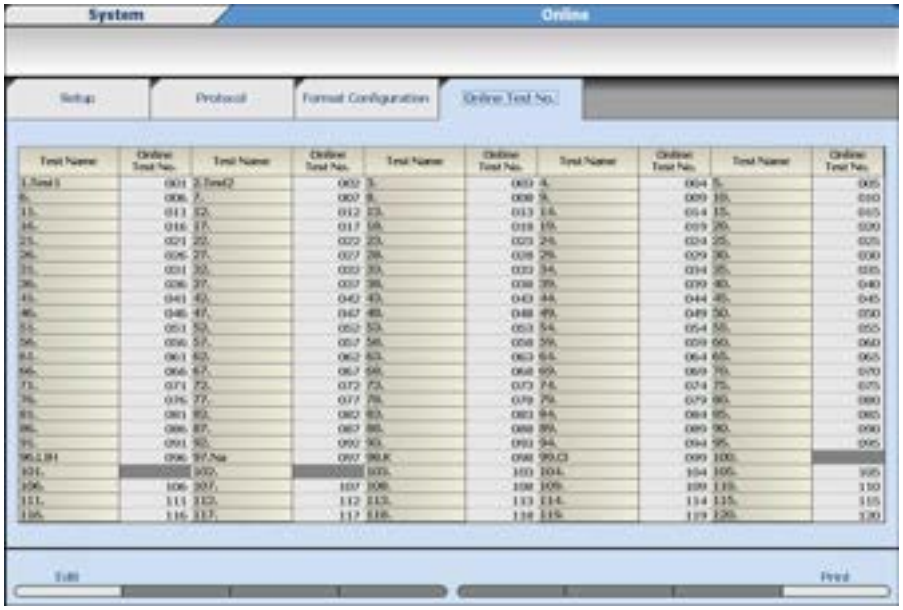
NOTE

Total and direct bilirubin are programmed as sample blank tests. For more information, refer to Test Name Screen.

For the blank test in sample blank tests, it is not possible to program an Online Test No. because the blank test result is only used for the calculation and is not a reported result.

1 Select **Menu List > System > Online > Online Test No**.

Figure 2.64 Online: Online Test No. Tab



2 Select **Edit (F1)**.

3 Move the cursor to the test name to be programmed.

4 Enter the **Online Test No.** The combination of the online test number and test must coincide with the laboratory information system. Set the number as a blank when online communication is not required.

NOTE

When the test number of the laboratory information system and the online test number differ, the data may not be transmitted correctly.

5 Repeat steps 3 to 4 for each test to be programmed.

6 Confirm that the information is correct, and then select **Confirm (F1)**.

7 When numbers are duplicated, the Parameter Error(s) dialog displays. Select **Cancel** and correct.

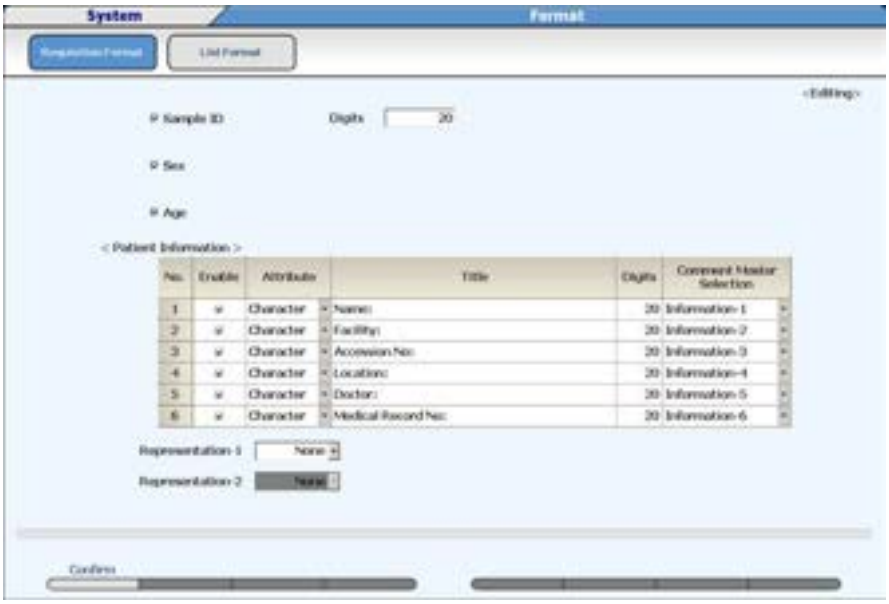
Format Menu

Program the test order (requisition) format including sample ID and demographic information.

Information programmed in **Requisition Format** is part of the data communication protocol, and impacts LIS communication.

1 Select **Menu List > System > Format > Requisition Format**.

Figure 2.65 Format: Requisition Format Screen



2 Program the requisition format for each item in the table.

Table 2.44 Requisition Format Description

Item	Contents	Input Notes
Sample ID	Check or no check	Select to enable Sample ID in **Home > Rack Requisition Sample > Sample** and **STAT Status > Sample**.

Table 2.44 Requisition Format Description (Continued)

Item	Contents	Input Notes
Digits	4 to 26	The number of digits entered here affects how many digits can be entered for the Sample ID in **Home > Rack Requisition Sample > Sample** and **STAT Status > Sample**, and the sample ID field length for the laboratory information system online records. The number of sample ID digits and bar code parameters are programmed in **Menu List > System > System Condition**. The number of digits should be greater than or equal to the digits in **System Condition**.
Sex	Check or no check	Select **Sex** to enable Sex in **Home > Rack Requisition Sample > Sample > Demographics** and **STAT Status > Sample > Demographics**, or receive the information from the LIS. Affects the laboratory information system online records.
Age	Check or no check	Select **Age** to enable Age in **Home > Rack Requisition Sample > Sample > Demographics** and **STAT Status >Sample >Demographics**, or receive the information from the LIS. Affects the laboratory information system online records.
Patient Information		A maximum of 6 patient demographics can be programmed for entry in **Home > Rack Requisition Sample > Sample > Demographics** and **STAT Status > Sample > Demographics**. Affects laboratory information system online records.
Enable	Check or no check	Select to enable programming for patient demographics No. 1 to 6.
Attribute	Character or Numeric	Program if letters or numbers are required for entry in **Home > Rack Requisition Sample > Sample > Demographics** and **STAT Status > Sample >Demographics** for Patient Information. Select **Character** to enter letters. Select **Numeric** to enter numbers for calculated tests and checked tests.
Title	A title name	Enter a maximum of 20 characters that display as the Patient Information title in **Sample > Demographics**.

Table 2.44 Requisition Format Description (Continued)

Item	Contents	Input Notes
Comment Master Selection	Information-1 to Information-6	Program **System > Comment Master** Attribute with Information -1 to Information-6. The master comment can then be selected in **Sample > Demographics**.
Representation-1 and Representation-2	1 to 6	Select from Patient Information No. 1 to 6 for the Title to appear in **Home > Sample Status**.

Example of Representation-1 and Representation-2 Options

Figure 2.66 Sample Status without Representation-1 or Representation-2 Programmed

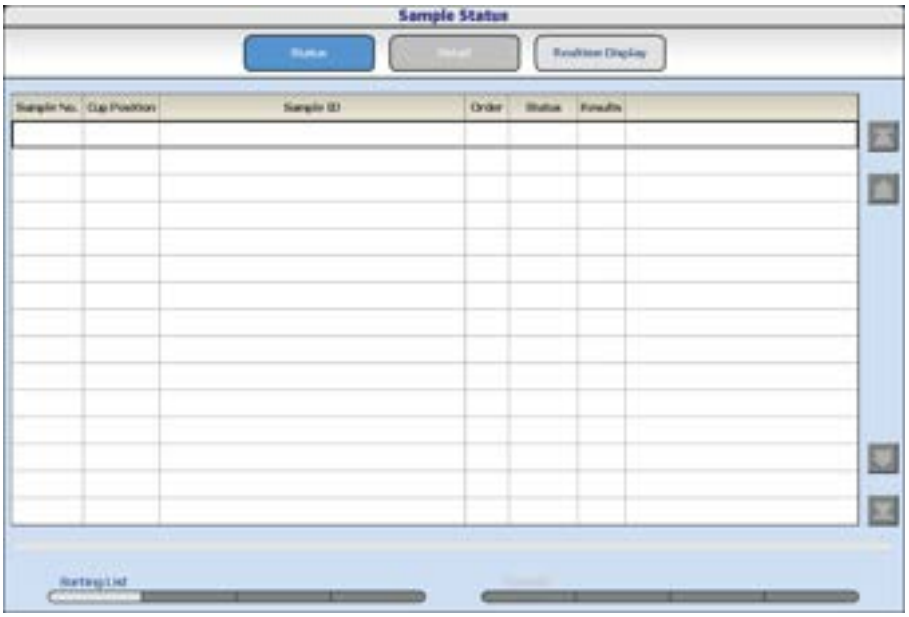
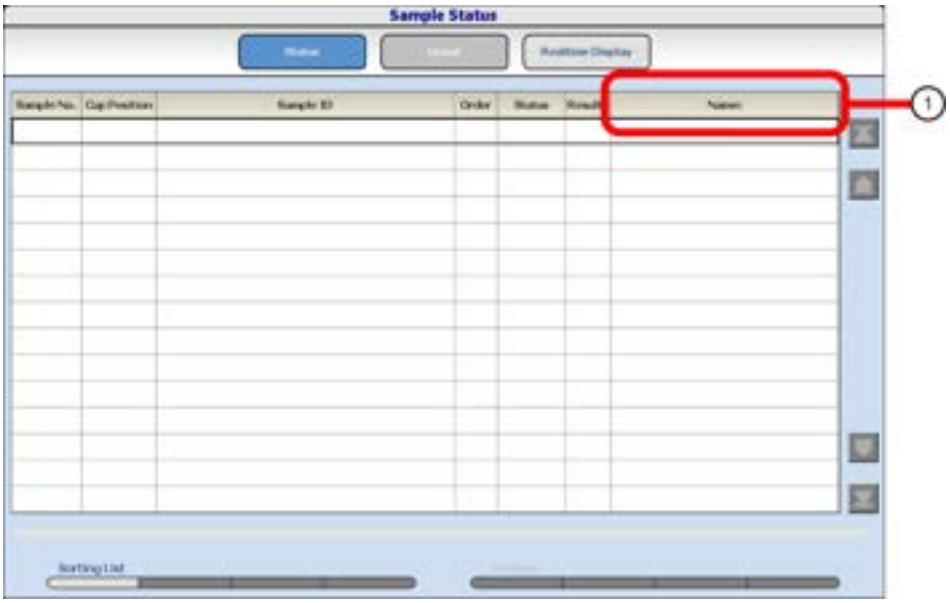
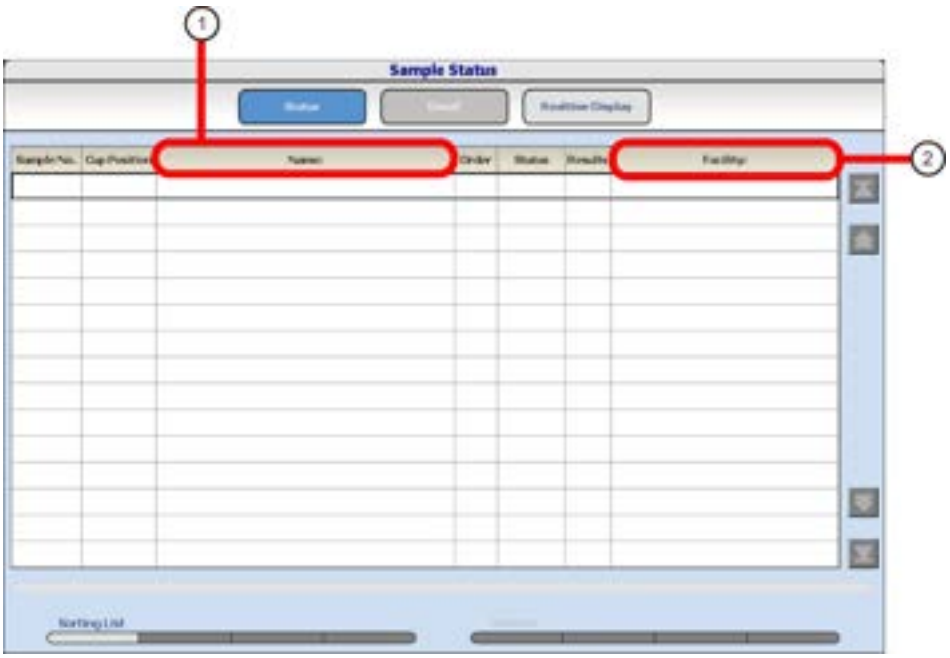


Figure 2.67 Sample Status with Representation-1 Programmed and Representation-2 Not Programmed



1. Representation-1

Figure 2.68 Sample Status with Representation-1 and Representation-2 Programmed



1. Representation-1
2. Representation-2

Print Formats

All realtime reports and data logs for reagent blank, calibration, QC, and samples, as well as worklists, pending lists, and repeat lists must be formatted before they are available to print.

A maximum of 15 formats can be programmed using seven available types of print layouts.

Printing reports is optional.

List Types Available in Specific Menus

Table 2.45 List Types

	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List
Applicable lists	Requisition Sample	Work list						
		Pending list						
	Repeat Order						Work list	
							Pending list	
	Repeat Data Verification							Repeat data list
	Sample Manager > Sample	Abnormal value list	Abnormal value list		Abnormal value list	Abnormal value list		
		Data List	Data List					
					Report	Report		
	Sample Manager > RB/QC/CAL			Data list				
	List Format > Realtime List (F5)		Patient	RB/CAL/QC	Patient	Patient		

Format Parameters for Each List Type

List of possible output settings for each list type

- * Required output item
- o Selective output item
- x Selection not possible

Table 2.46 Output Settings for Each List Type

List Type	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List
Basic Condition	List Name	Within 20 single-byte characters						
	Data Format	6/9	6/9	6/9	6/9	6/9	6/9	6/9
	Data Justify	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left	Right/ Left
	Patient Sample	o	o	x	x	x	o	o
	Calibration Sample	x	x	o	x	x	x	x
	RB Sample	x	x	o	x	x	x	x
	QC Sample	x	x	o	x	x	x	x
	Sheet Number[1, 4]	x	x	x	1 to 4	1 to 4	x	x
	Character in sheet[2 4]	x	x	x	o	o	x	x
	Form Method of Item Name[3, 4]	x	x	x	o	o	x	x
	Number of Data Flag	x	x	x	1 to 4	1 to 4	x	x
	Form Method of Unanalysis Data	x	x	x	o	x	x	x
	Change Page	x	x	x	o	o	x	x
	Line	x	x	x	o	o	x	x
	Fixed Comment	x	x	x	o	o	x	x

Table 2.46 Output Settings for Each List Type (Continued)

List Type	Menu	Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type		Repeat List		Repeat Data List	
Page Header	Header Width[4]	1 to 10 (lines of the form header)													
	Device No.	•	•	•	•	•	•	o	o	o	o	•	•	•	•
	List Name	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Page	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Index	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Group	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Print time	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Operator	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Reporter	o	o	o	o	o	o	o	o	o	o	o	o	o	o
Sample information	Sample Width[4]	1 to 10 (lines of the form header)													
	S. No.	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Org S. No.	x	x	x	x	x	x	o	o	o	o	o	o	o	o
	Rack No. - Cup Pos.	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	S. ID	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Sex	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Age	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Month	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Type	o	o	o	o	o	o	o	o	o	o	o	o	o	o
	Patient Inf. 1 to 6	o	o	o	o	x	x	o	o	o	o	o	o	o	o
	Patient Comment	x	x	x	x	x	x	o	o	o	o	x	x	x	x
	Sample Name	x	x	x	x	o	o	x	x	x	x	x	x	x	x
	Kind No.-Seq. No.	x	x	x	x	o	o	x	x	x	x	x	x	x	x
	Lot No.	x	x	x	x	o	o	x	x	x	x	x	x	x	x

Table 2.46 Output Settings for Each List Type (Continued)

List Type	Menu	Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type		Repeat List		Repeat Data List	
Item Information	Item Name	x	•	x	o	x	•	x	o	x	o	x	•	x	o
	Test Data	x	o	x	•	x	•	x	•	x	•	x	x	x	•
	Data Flags	x	o	x	o	x	o	x	o	x	o	x	x	x	o
	R. Bottle Inf.	x	o	x	o	x	x	x	o	x	o	x	x	x	o
	Unit	x	x	x	x	x	x	x	o	x	o	x	x	x	x
	Normal Range	x	x	x	x	x	x	x	o	x	o	x	x	x	x
	Output	o	o	o	o	x	x	x	x	x	x	x	x	x	x
Tail Information	Total Tests	o		o		x		x		x		x		o	
	Total Samples	o		o		x		x		x		o		o	
	Reagent Consumption	o		o		x		x		x		o		o	
	Tail name	o		o		x		x		x		o		o	

1. Set the number of samples to print on one form sheet.
2. The maximum number of characters per line differs according to the Print Direction, the Paper Size, and the Sheet Number.
   - — Portrait A4 1 sheet 136 characters per line
   - — Landscape A4 1 sheet 168 characters per line
   - — Portrait A3 1 sheet 192 characters per line
   - — Landscape A3 1 sheet 240 characters per line
   - — Portrait Letter 1 sheet 136 characters per line
   - — Landscape Letter 1 sheet 156 characters per line
   - — Portrait Tabloid 1 sheet 180 characters per line
   - — Landscape Tabloid 1 sheet 240 characters per line
   - — Portrait Legal 1 sheet 136 characters per line
   - — Landscape Legal 1 sheet 192 characters per line
   - — For two sheets or more, the above number of lines is the number of lines divided by the sheet number.
3. Program whether the abbreviated name or long name is to be used as the Test Name.

4. The layout setting is cancelled when the Print Direction, the Paper Size, the Sheet Number, the Character in sheet, the Header Width, or the Sample Width is changed. Program the layout again.

Layout Setting Parameters

Table 2.47 Layout Setting Parameters

	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type	Repeat List	Repeat Data List
Layout	Page Header	o	o	o	o	o	o	o
	Sample Information	o	o	o	o	o	o	o
	Item Information	x	x	x	o	o	x	x

For the Result (Fix) Type, the test information print position is formatted to a specific column and line for each test.

For the Result (Seq.) Type, the start position for printing test information is set. The specific tests requisitioned on a sample start printing in consecutive lines at the formatted start print position.

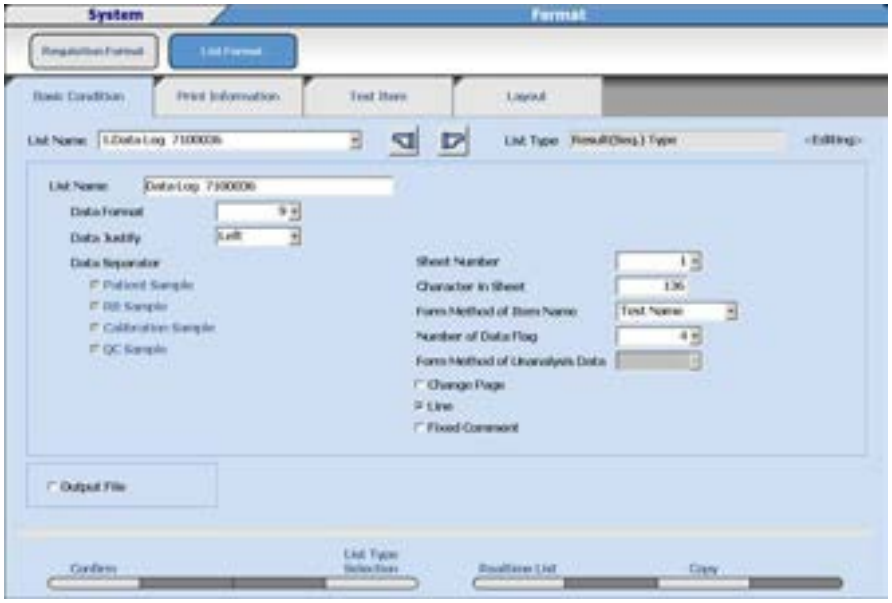
For types other than Result Type, the test information print position cannot be set.

Format Realtime Reports and Lists

Program the format parameters for realtime reports and lists.

1 Select **Menu List > System > Format > List Format > Basic Condition**.

Figure 2.69 List Format: Basic Condition Tab



2 Select **Edit (F1)**.

3 Select the List No. to be formatted from **List Name**.

4 For List Name, enter a list name with a maximum of 20 characters.

5 Select **List Type Selection (F4)** to change the list type. The List Type Selection dialog opens.

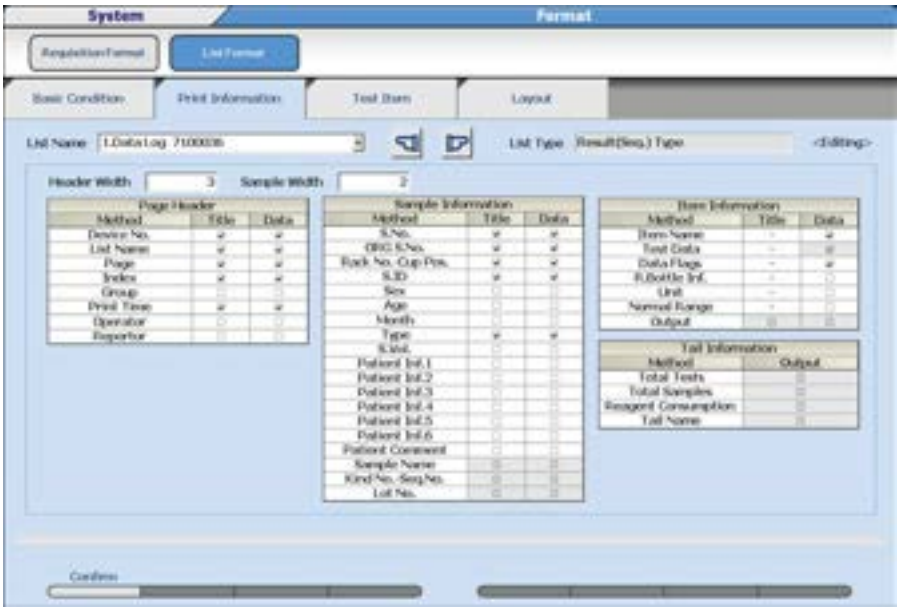
6 Select the list type from **List Type**.

7 Select **OK**.

8 Select or enter the required setting items on the list format.

9 Select the **Print Information** tab.

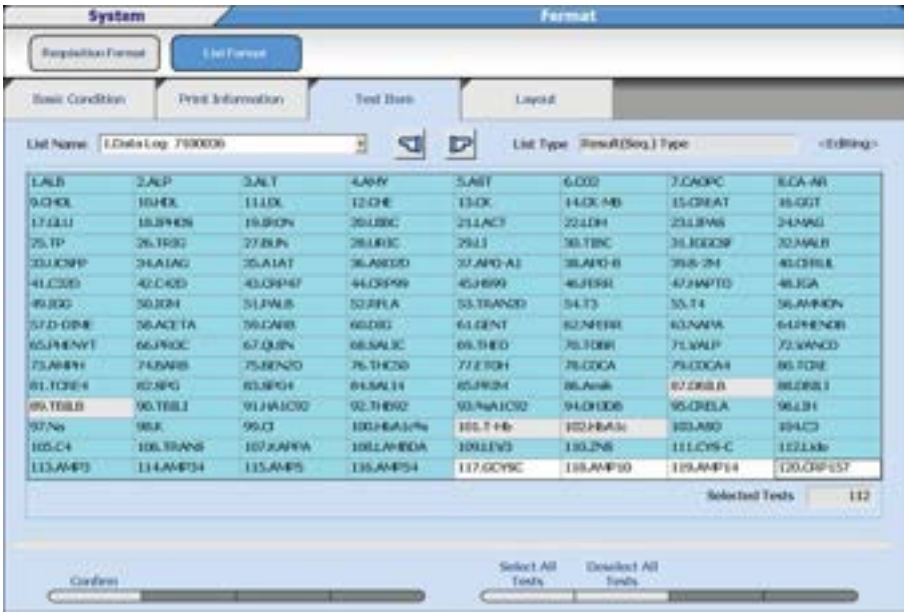
Figure 2.70 List Format: Print Information Tab



10 Select the information to print on the list.

11 Select the **Test Item** tab.

Figure 2.71 List Format: Test Item Tab



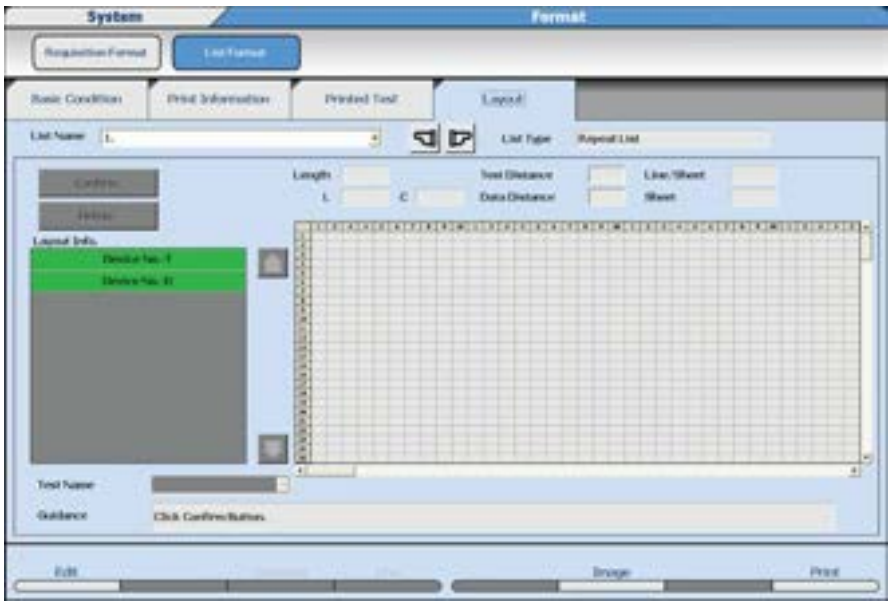
12 Select the tests to print.

The selected tests change to blue. The number of selected tests displays on the lower-right of the screen.

Select **Select All Tests (F5)** and **Deselect All Tests (F6)** as required.

13 Select the **Layout** tab.

Figure 2.72 List Format: Layout Tab



14 Select the item to print from **Layout Info.**. Items that can be selected have been programmed to print in the Print Information tab. This includes the Page Header, Sample Information, Item Information, Comment, and Line options.

15 Select **Confirm**. Move the cursor to the column and line on the grid to start printing the selected item. Select **Set**. The position selected to start printing the item is displayed in a blue box, and the rest of the information for the item is displayed in yellow boxes.

Repeat steps 14 and 15 for all layout information.

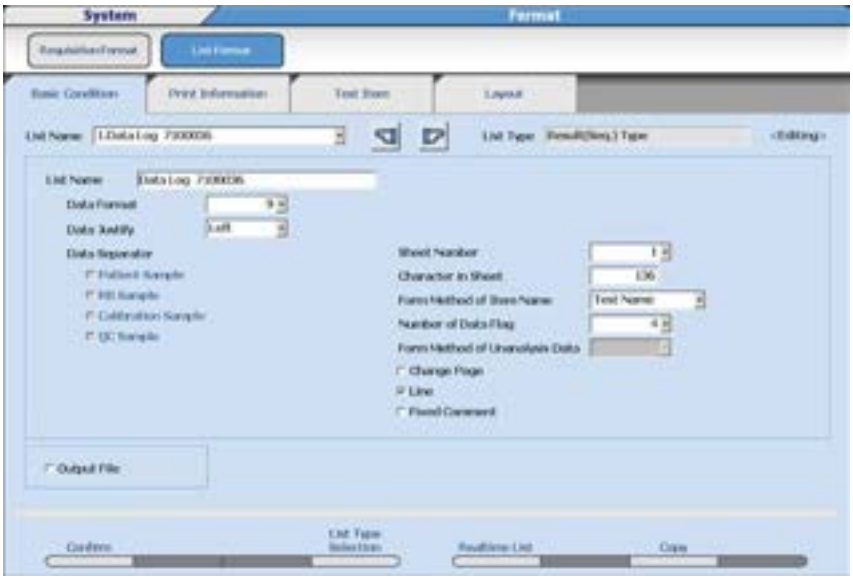
16 Confirm that the information is correct, and then select **Confirm (F1)**.

Program Realtime Print Options

Program a realtime print format for samples, reagent blank, calibration, and QC. The appropriate List Type must be formatted for samples, reagent blank, calibration, and QC before it is available to print realtime.

1 Select **Menu List > System > Format > List Format > Basic Condition**.

Figure 2.73 List Format: Basic Condition Tab



2 Select **Edit (F1)**.

3 Select **Realtime List (F5)**. The Realtime List dialog opens.

Figure 2.74 Realtime List Dialog

Table 2.48 Realtime List Dialog Description

Option	Description
Data Log	Select to enable realtime printing.
Data Log Format	Select the list name for Patient, Calibration, Reagent Blank, and QC.
Quick Output	When selected, one sample prints when it is complete per page.
Quickly	When selected, quick test results from samples processed on the STAT table are printed before the normal print time for all tests on a sample. Quick test results are those with R1 only (read points before P10) and ISE tests.

4 Select **Data Log**.

5 Select the print format from **Patient**, **Calibration**, **Reagent Blank**, and **QC**.

6 Select samples for Quick Output.

7 Select **OK**. The Realtime List dialog is closed.

8 Confirm that the information is correct, and then select **Confirm (F1)**.

Save Data to a File

Data is saved to an AU680_List_Image.txt file, and does not print realtime when Output File is selected.

1 Select **Menu List > System > Format > List Format > Basic Condition**.

2 Select **Output File**.

Copy Format Parameters

Format parameters from one list can be copied to an available list number.

1 Select **Menu List > System > Format > List Format > Basic Condition**.

2 Select **Edit (F1)**.

3 Select an available list number (place to copy another list) from **List Name**.

4 Select **Copy (F7)**. The Copy dialog opens.

5 Select the list to be copied from **List Name**.

6 Select **OK**. The list parameters are copied.

7 Enter a list name for the copied list in **List Name**.

Add or Change a Comment

The Fixed Comment option must be checked in the Basic Condition tab before **Layout > Comment (F3)** is accessible.

1 Select **Menu List > Format > List Format > Layout**.

2 Select **Edit (F1)**.

3 Select **Comment (F3)**.

4 Enter a comment (maximum of 20 characters) in **Comment**.

5 Select **Horizontal** or **Vertical** in Direction.

6 Select **OK**.

7 Select the Comment from **Print Info.**. The squares available to format the selected item display in white.

8 Select the **Confirm** button. Move the cursor to the position on the grid to start printing the selected item. Select the **Set** button. The position selected to start printing the item is displayed in a blue box, and the rest of the information for the item is displayed in yellow boxes.

9 Confirm that the information is correct, and then select **Confirm (F1)**.

Lipemia, Icterus, and Hemolysis (LIH)

LIH Reagent OSR62166 is a photometric test for the semi-quantitative assessment of lipemia/turbidity, icterus, and hemolysis (LIH) in human serum and plasma on the AU analyzer.

A number of diseases and pre-analytical conditions can result in increased concentrations of chromogens like bilirubin, hemoglobin, and lipids/turbidity in body fluids. Chromogens can interfere with photometric tests.

Patient samples are diluted with the LIH reagent and the absorbance is measured at six wavelengths. If one or more chromogen in a potentially interfering concentration is present in a sample, applicable flags are generated and reported along with the results of the sample. These flags characterize the kind of chromatic substance (LIP: lipemia/turbidity, ICT: bilirubin, HEM: hemoglobin) and the approximate concentration of the interferents.

The following table shows the approximate concentration of chromatic substance.

WARNING

The concentrations listed in the table are for reference only. Depending on the matrix effect with an individual serum sample, some results may not meet the listed concentrations.

Table 2.49 Approximate Concentration of Chromatic Substance

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	< 40	< 2.5	< 50
+	40 - 99	2.5 - 4.9	50 - 99
++	100 - 199	5.0 - 9.9	100 - 199
+++	200 - 299	10.0 - 19.9	200 - 299

Table 2.49 Approximate Concentration of Chromatic Substance (Continued)

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
++++	300 - 500	20 - 40	300 - 500
+++++	> 500	> 40	> 500

If a sample has one or more flags from the table, refer to the Interfering Substance section of the reagent IFU to verify the accuracy of the test results of that sample.

The AU680 can be programmed for Sample Specific LIH and Test Specific LIH. Sample Specific LIH tests the level of LIH in the sample. Test Specific LIH determines the effect this level of LIH has on individual tests.

1. Sample Specific LIH: The level of lipemia, icterus, or hemolysis is optically identified by measuring the sample and LIH Reagent in the cuvette. Based on the programmed absorbance limits for Lipemia, Icterus, and Hemolysis in the LIH Test, a flag is generated for each interfering substance as N (normal), +, ++, +++, ++++, +++++, or ABN (abnormal).

   Each sample displays the results of the LIH Test. For example:

   — LIP +
   — ICT N
   — HEM ++
2. Test Specific LIH: The level of lipemia, icterus, or hemolysis in the sample is used to determine the effect on individual tests. Each specific test is programmed to generate l, i, or h flags if the Lipemia, Icterus, or Hemolysis limit is exceeded. For example, a DBIL that is affected by the level of hemolysis in the sample:

   — DBIL 0.3 h

ISE tests (Na, K, and Cl) are not evaluated for test specific LIH.

LIH Reagent

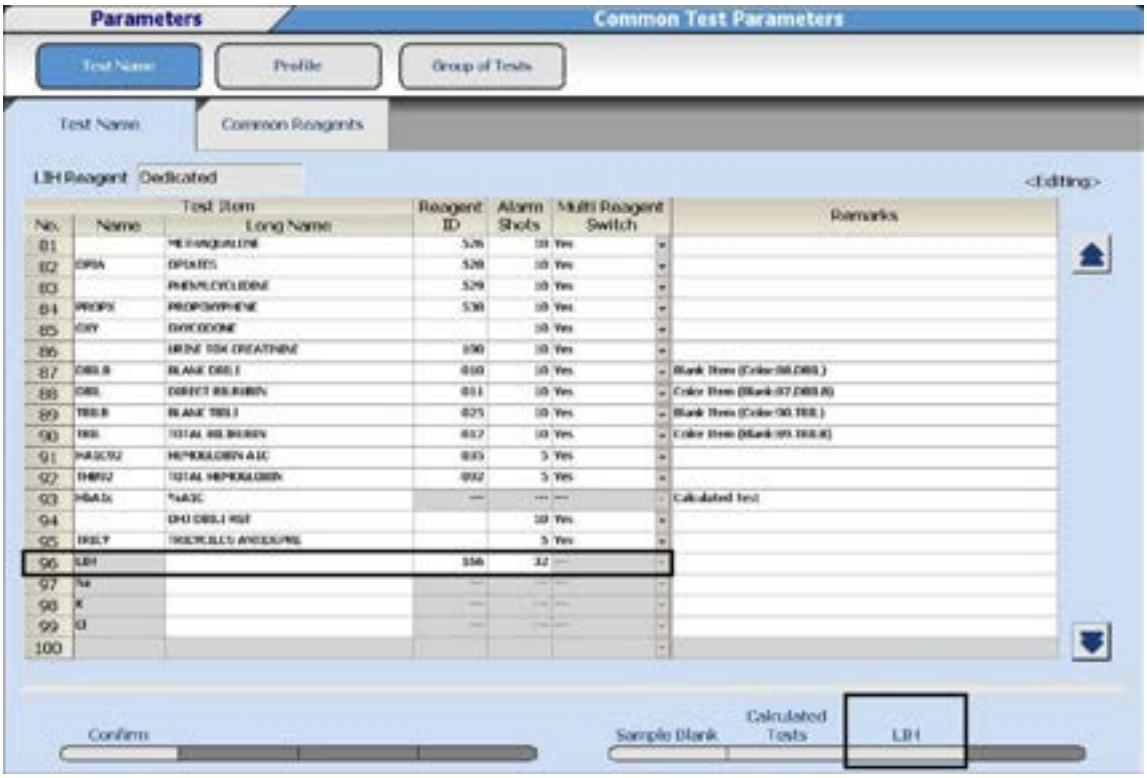
LIH Reagent (OSR62166) is the only reagent validated for test specific LIH testing.

The LIH Reagent is supplied in a 60 mL bottle with a reagent ID, R1 only. The kit configuration is 2400 tests per bottle and 16 bottles per kit. The Onboard Stability is 90 days.

Program LIH

1 Select **Menu List > Parameters > Common Test Parameters > Test Name > Test Name**.

Figure 2.75 Test Name: Test Name Tab



a. Select **Edit (F1)**.

b. Scroll down to No. 96.

c. For Reagent ID, enter 166.

d. For Alarm Shots, enter the remaining shots (tests) to generate a Reagent Short alarm. The default is 32.

e. Select **LIH (F7)**.

f. Confirm **LIH Reagent** is set to Dedicated.

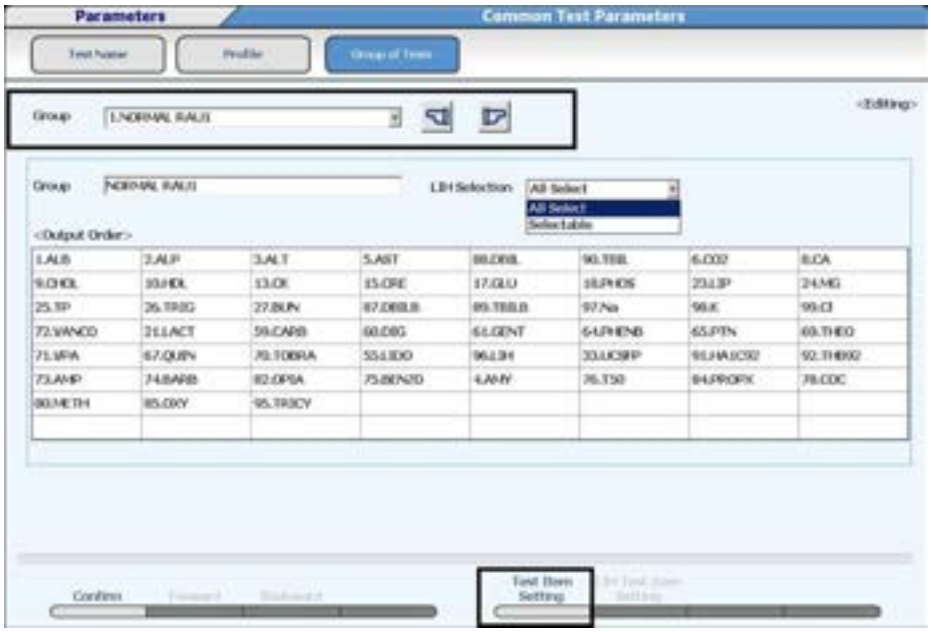
Figure 2.76 LIH Dialog

g. Select **Close**.

h. Confirm that the information is correct, and then select **Confirm (F1)**.

i. Select the **Group of Tests** screen.

Figure 2.77 Common Test Parameters: Group of Tests Screen



j. Select Group 1, 2, or 3 from **Group** list to add LIH.

k. Select **Edit (F1)**.

l. Select **All Select** or **Selectable** in **LIH Selection**.

— Select **All Select** to automatically order (requisition) LIH on every sample.
— Select **Selectable** to order (requisition) LIH as needed on each sample.

m. Select **Test Item Setting (F5)**.

n. Select (highlight) **Test 96**. LIH and then select **Close**.

o. Confirm LIH displays under **<Output Order>**.

p. Repeat for multiple Groups if needed.

q. Confirm that the information is correct, and then select **Confirm (F1)**.

---

2 Select **Parameters > Specific Test Parameters > LIH**.

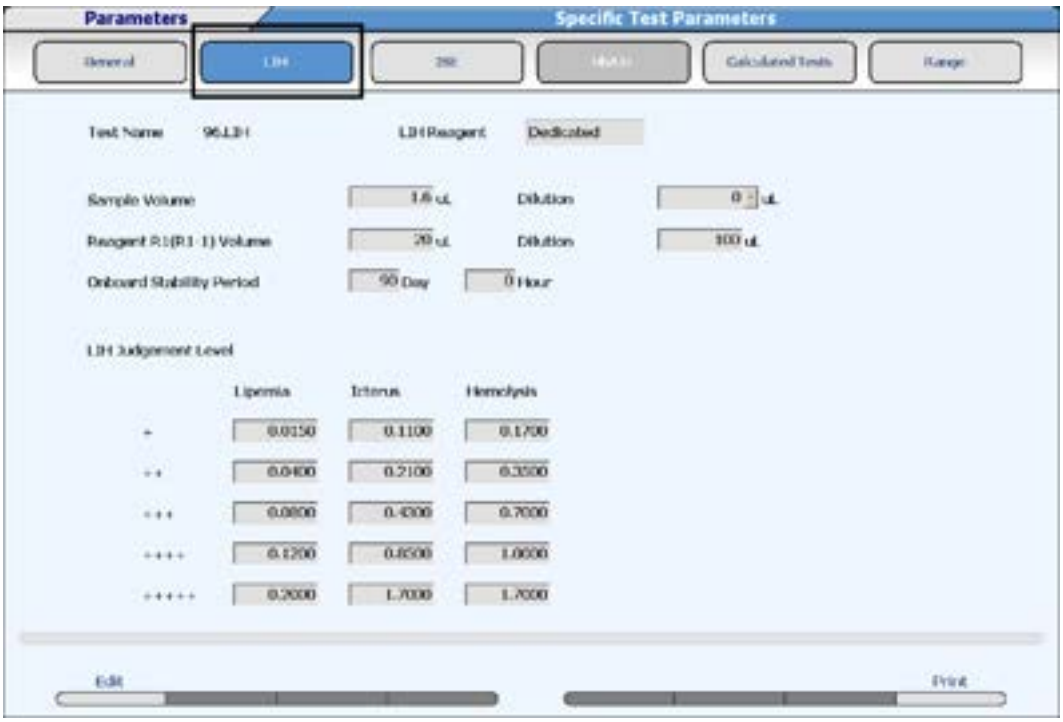
NOTE

Program 96. LIH Test using the LIH chemistry setting sheet. Sample Specific LIH limits are determined by the LIH Test parameters entered in this LIH screen.

Parameter values found on the LIH chemistry setting sheet are only valid if using LIH Reagent OSR62166.

— Select **Edit (F1)**.
— Enter the parameters found on the LIH chemistry setting sheet.
— Confirm that the information is correct, and then select **Confirm (F1)**.

Figure 2.78 Specific Test Parameters: LIH Screen



3 Select the **General** screen.

NOTE

97. Na, 98. K, and 99.Cl are inaccessible (grayed out) and cannot be programmed for test specific LIH criteria. ISE tests are not evaluated for LIH.

LIH Influence Check only displays for programming for Serum sample type. Any values programmed affect Other-1 and Other-2 sample types, if System Maintenance is enabled for Other-1 and Other-2.

a. Select **Edit (F1)**.

— In **Test Name**, select a test to program test specific LIH parameters. For an example, in Figure 2.79 Specific Test Parameters: General Screen, DBIL is selected in**Test Name**.

— Select **Yes** in **LIH Influence Check** to perform test specific LIH analysis. Select **No** in **LIH Influence Check** if test specific LIH analysis is not required for a test.

— Refer to the chemistry setting sheet for each specific test for the test specific LIH parameters. For this example in Figure 2.79 Specific Test Parameters: General Screen, refer to the Direct Bilirubin (DBIL) chemistry setting sheet.

— Repeat for all tests on the Groups.

— Confirm that the information is correct, and then select **Confirm (F1)**.

Figure 2.79 Specific Test Parameters: General Screen

4 Select **Menu List > System > Format > List Format > Test Item**.

— Select **Edit (F1)**.
— Select LIH to add it to all required printouts and lists. **List Name** contains a list of all the realtime printouts and lists available.

5 Confirm that the information is correct, and then select **Confirm (F1)**.

Running the LIH Test

- Only one additional cycle time (4.5 seconds) per sample is required to run the LIH test.
- Place the bar coded LIH reagent bottle in the R1 refrigerator and follow procedures for checking reagents.
- LIH may be programmed for automatic order (requisition) on all samples or may be ordered (requisitioned) on individual samples as needed. If LIH is programmed for automatic order (requisition) all samples, LIH is highlighted in blue in **Home > Rack Requisition Sample**. Order (requisition) LIH using normal order (requisition) procedures. LIH can be ordered (requisitioned) by realtime query with the LIS, or manually.
- LIH results print automatically after programming.
- LIH criteria only apply to Serum/Plasma, Other-1, and Other-2 sample types. For Urine sample types, the LIH test is grayed out and is not operational.

CHAPTER 3

Sample Programming and Processing

Cautions with Cups or Tubes Specifications

WARNING

Use only sample cups and tubes listed in the specifications and recommended by Beckman Coulter. If other cups or tubes are used, analysis cannot be performed, or errors can result.

NOTE

BD indicates a Becton Dickinson PN. The BD tube or its equivalent can be used.

Cup or Tube Available for Racks or STAT Table

Table 3.1 Cup or Tube Available for Racks or STAT Table

Cup or Tube	Size	PN	Dead Volume (µL)
Hitachi cup	2.0 mL	MU853200	50
Auto aliquot tube	13 mm	2910034	80
Serum Separator Tube	13 x 100 mm	BD 367986	4 mm above the non-sample (cells or gel) layer
Serum Separator Tube	16 x 100 mm	BD 367988	4 mm above the non-sample (cells or gel) layer
Lithium heparin with gel separator (light green top)	13 x 75 mm	BD 367960	4 mm above the non-sample (cells or gel) layer
Lithium heparin with gel separator (light green top)	13 x 100 mm	BD 367962	4 mm above the non-sample (cells or gel) layer
Lithium heparin (green top)	13 x 75 mm	BD 367884	4 mm above the non-sample (cells or gel) layer
Lithium heparin (green top)	13 x 100 mm	BD 367886	4 mm above the non-sample (cells or gel) layer
Primary tube (red top)	13 x 75 mm	BD 366668	140

Table 3.1 Cup or Tube Available for Racks or STAT Table (Continued)

Cup or Tube	Size	PN	Dead Volume (µL)
Primary tube (red top)	13 x 100 mm	BD 367815	140

Cup Nested (Inserted) in Tube Available for Racks

Table 3.2 Cup Nested (Inserted) in Tube Available for Racks

Cup, Size	PN	Tube	PN	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	50
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
Access 2 cup, 1.0 mL	81915	13 x 100 mm	BD 367962 BD 367886 BD 367815	140
Hitachi cup, 2.0 mL	MU853200	SST 16x100 mm	BD 367988	50
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	50
EZ Nest cup	1270013000	13 x 100 mm	BD 367962 BD 367886 BD 367815	50
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50
EZ Nest cup	1270016000	16 x 100 mm	BD 367988	50

Cup Nested (Inserted) in Tube Available for STAT Table

Table 3.3 Cup Nested (Inserted) in Tube Available for STAT Table

Cup, Size	PN	Tube	PN	Dead Volume (µL)
DxC cup, 2.0 mL	652730	DxC transfer	979272	50
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50

Table 3.3 Cup Nested (Inserted) in Tube Available for STAT Table (Continued)

Cup, Size	PN	Tube	PN	Dead Volume (µL)
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	50
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50

Cup or Tube Restrictions for Racks

The analyzer has five sensors to detect the height of the cup or tube in a rack. The following restrictions apply when using more than one cup or tube simultaneously:

1. One type of cup or tube can be selected for each sensor.
2. More than one type of cup or tube can be selected for each sensor only if the cup or tube is the same Level: A, B, C, D, E, or F.

WARNING

If more than one type of cup or tube is in use for a sensor, and the cup or tube is a different level (A, B, C, D, E, or F):

- **If the maximum probe stroke is programmed to the shortest cup or tube, it is possible to aliquot no sample or the dead volume is increased from longest cup or tube.**
- **If the maximum probe stroke is programmed to the longest cup or tube, the shortest cup or tube must contain sufficient sample to avoid a probe crash.**
- **If the AU680 is connected to a laboratory automation system, the probe can have only one probe downward stroke programmed, and only one type of sample tube or cup can be used.**

Table 3.4 Cup or Tube Restrictions for Racks

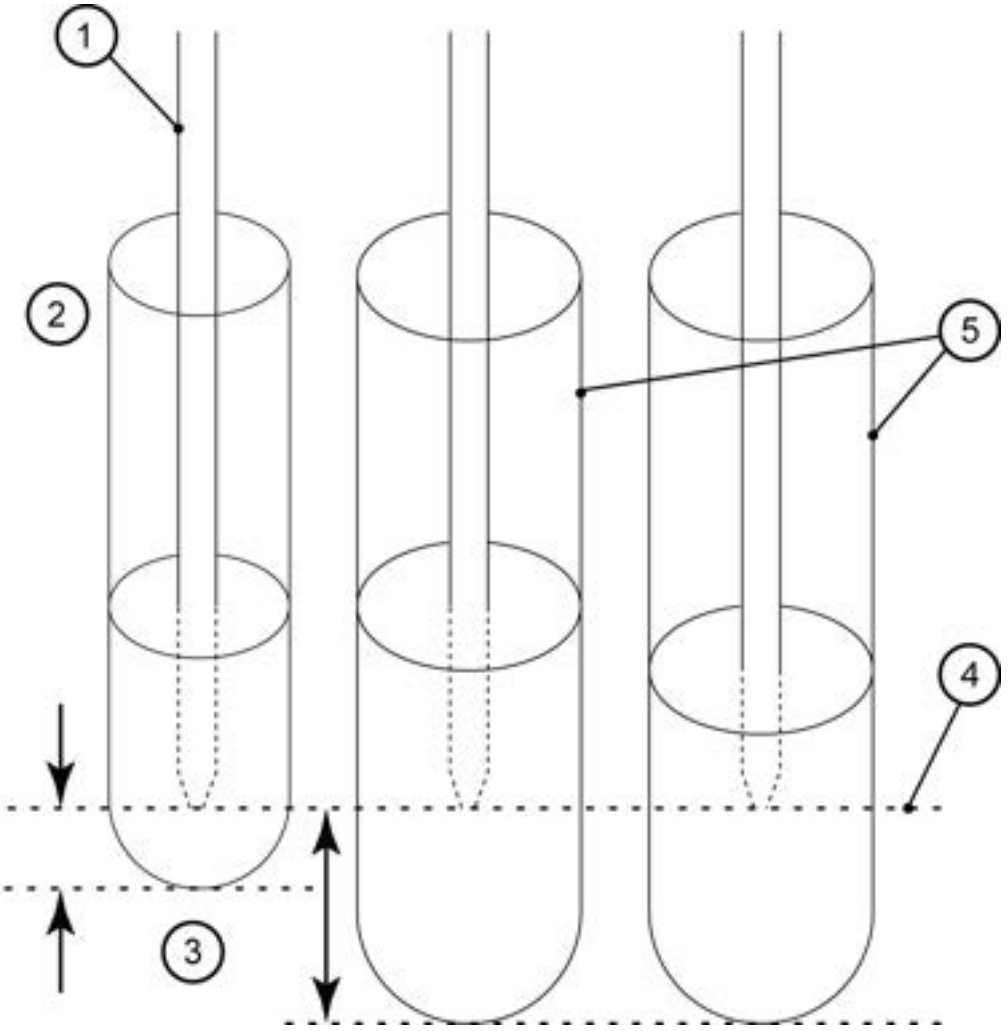
Sensor	Level	Cup or Tube		Tube
1	A	Hitachi cup	MU853200	

Table 3.4 Cup or Tube Restrictions for Racks (Continued)

Sensor	Level	Cup or Tube		Tube
2	A	Lithium heparin with gel separator (light green top)	BD 367960	
	A	Lithium heparin (green top)	BD 367884	
	A	Primary tube (red top)	BD 366668	
	B	DxC cup	652730	DxC transfer tube (979272)
	C	Access 2 cup	81902	
	D	Access 2 cup	81915	13 x 75 mm tube
	E	EZ Nest cup	1270013000	
	F	EZ Nest cup	1270016000	16 x 75 mm tube
3	A	Hitachi cup	MU853200	16 x 75 mm tube
4	A	Serum Separator Tube	BD 367986	
	A	Lithium heparin with gel separator (light green top)	BD 367962	
	A	Lithium heparin (green top)	BD 367886	
	B	Auto aliquot tube	2910034	
	C	Access 2 cup	81915	13 x 100 mm tube
	D	EZ Nest cup	1270013000	
	E	EZ Nest cup	1270016000	16 x 100 mm tube
5	A	Hitachi cup	MU853200	16 x 100 mm tube

The default probe setting in the software for each cup and tube is Level A. If using a cup or tube other than Level A, contact Beckman Coulter. Beckman Coulter must make probe setting changes.

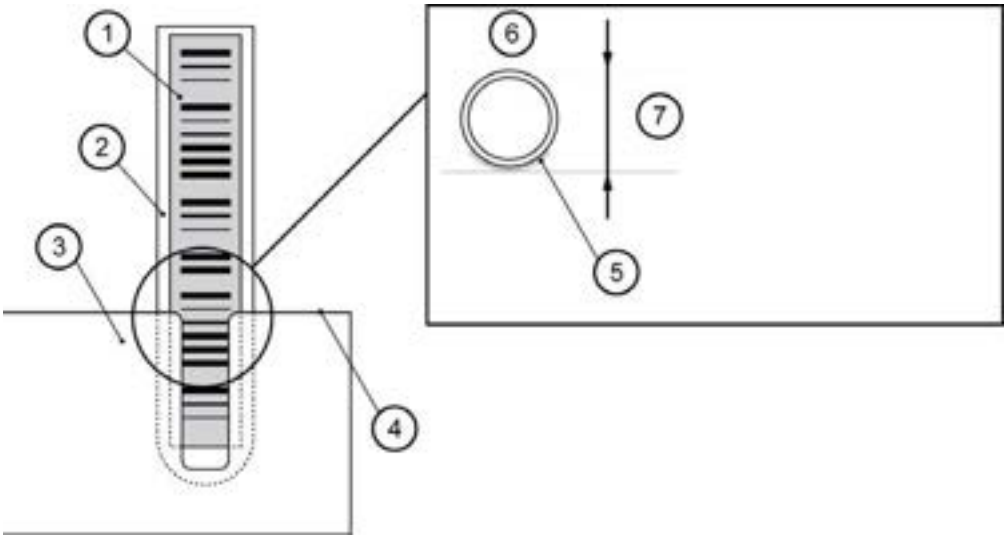
Figure 3.1 Sample Probe Stroke and Cup or Tube Height



1. Sample probe
2. Shortest cup or tube
3. Dead volume
4. Maximum probe downward stroke
5. Longest cup or tube

The maximum outer tube or cup diameter is 16 mm, including a sample bar code label. If the tube or cup has a protrusion or lip at the top, the maximum outer diameter is 17.5 mm. If the diameter is greater than 17.5 mm, the tubes interfere when placed next to each other in the rack.

Figure 3.2 Maximum Outer Cup or Tube Diameter



1. Bar code label
2. Sample tube
3. Rack
4. Rack top
5. Bar code label
6. Top view
7. 16.0 mm or less (outside diameter including the bar code label)

Cup or Tube Restrictions for the STAT Table

WARNING

The analyzer has only one sensor to detect the cup or tube on the STAT table; therefore, only one maximum probe downward stroke can be programmed. The maximum probe downward stroke must be programmed for the cup or tube with the highest bottom position. If primary tubes and tubes with nested cups are both used on the STAT table, the nested cup must contain sufficient sample to avoid a probe crash into the nested cup.

Apply Bar Code Labels to Sample Tubes

WARNING

The bar code reader might not identify bar code labels that are too long or too short.

Bar code labels must not protrude from the top of a sample cup or tube. The label must be positioned perpendicularly. The angle can vary by a maximum of 5°.

For more information on bar code label specifications, refer to Sample Bar Code Specifications.

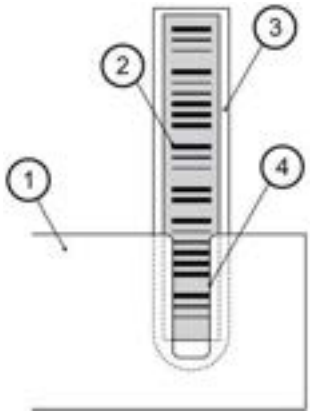
NOTE

Refer to the Laboratory Automation System manual for applying bar code labels to sample cups when the AU680 is connected to a laboratory automation system.

1 Affix the bar code labels to the outside of the sample tube so the end of each label is a minimum of 7 mm from the bottom of the cup, and the angle is within a maximum of 5°.

2 Rub the label gently using a finger to attach it firmly so that it does not peel off.

Figure 3.3 Sample ID Bar Code Label Application



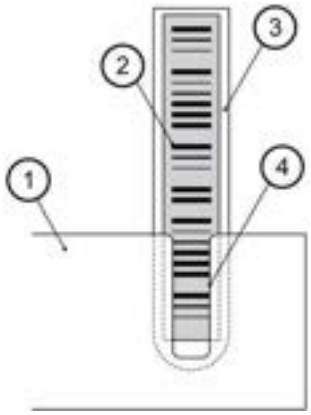
1. Bar code label
2. NE rack
3. The inclination angle must be 5° or less
4. Sample tube
5. 7 mm minimum

NE Racks

An NE rack has a slit to place the bar code label below the top surface of the rack. The NE rack allows for various tube diameters to be used with or without adapters. Use only NE racks on the AU680.

Racks that are not NE have a solid top surface with holes for the tubes with a set diameter.

Figure 3.4 NE Rack with Tube

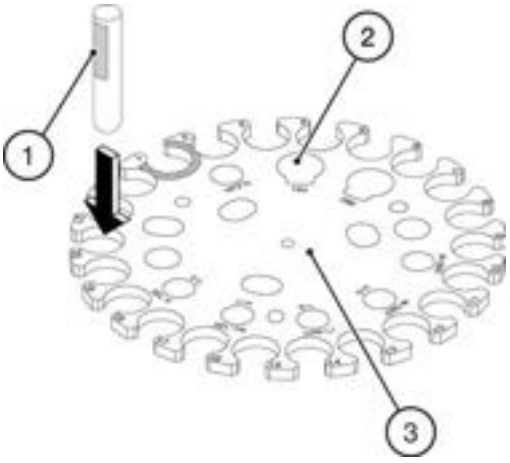


1. NE rack
2. Bar code label
3. Sample tube
4. Slit in NE rack

Bar Code Labels for STAT Table Analysis

Placing samples with bar code labels on the STAT table: The outer positions (1 to 22) are used for STAT analysis. Place the tube on the table with the bar code label facing out from the center of the table.

Figure 3.5 Placing Tubes with Bar Code Labels on the STAT Table



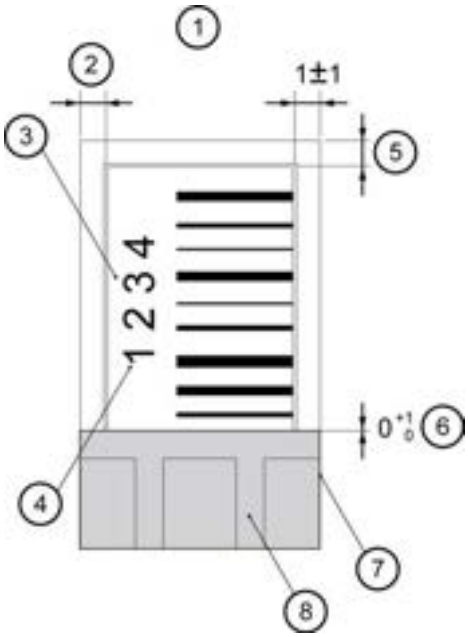
1. Place the tube in outer position 1-22 with the label facing out from the center of the table
2. The inner positions are not available for barcode analysis
3. STAT table

Applying a Rack ID Bar Code Label on the Rack

All racks (yellow, green, white, red, orange) except the blue rack require a bar code before they are processed.

Apply the rack ID label to the front (position 1 end) of the rack, perpendicular to the protruding part of the rack. Refer to the diagram below. The units are in mm.

Figure 3.6 Rack ID Bar Code Label Application



1. Rack front
2. The label should not stick out from the rack.
3. Rack ID label (Stick the label on the rack parallel with the side face.)
4. Orient the label so the numbers are located to the left if viewed from the front.
5. The label should not stick out from the rack.
6. The label cannot be placed on the protruding part of the rack.
7. Rack side
8. Protruding part of the rack

WARNING

Bar code labels in bad condition can cause them to be read incorrectly. Replace bar code labels if any of the following conditions are observed:

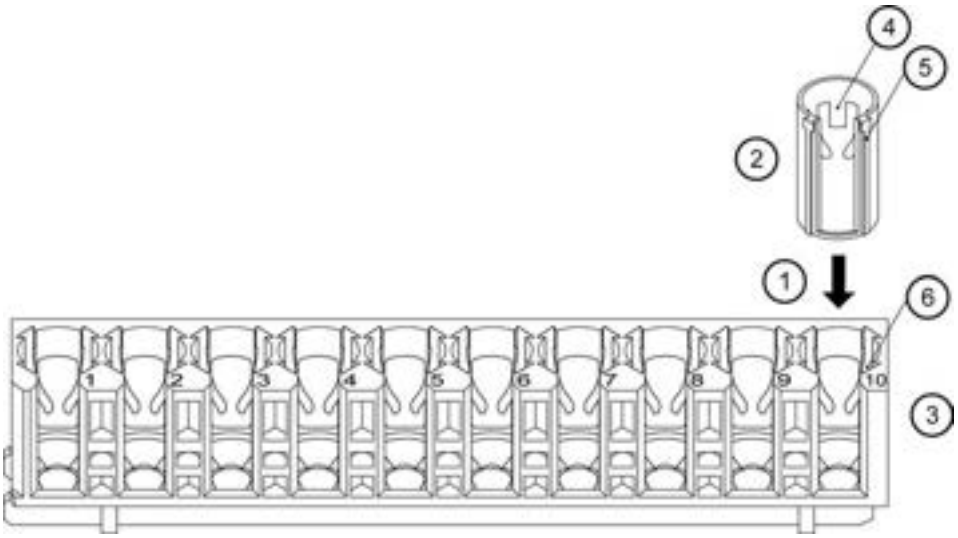
- **The bar code label is smudged, scratched, or damaged.**
- **The bar code is stained or dirty.**
- **The bar code label is torn or peeling.**

Use Adapters on Sample Racks

Adapters are necessary to hold smaller diameter tubes (approximately 11.5 to 13.5 mm) firmly in position in the racks. Larger diameter tubes (approximately 13.6 to 16 mm) do not require adapters. To confirm that a tube fits correctly, place the tube into a rack with and without an adapter and determine which option holds the tube most securely.

Insert an Adapter

Figure 3.7 Insert an Adapter into a Rack



1. Push in
2. Adapter
3. Rack
4. Adapter lock
5. Guide
6. Guide groove

1 Align the adapter opening and the rack opening.

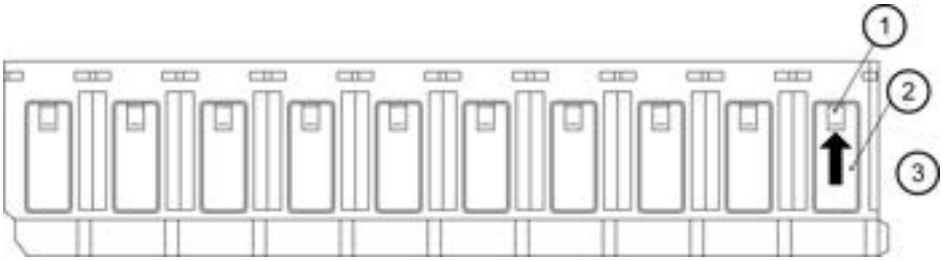
2 Insert the adapter guide into the guide groove of the rack.

3 Push the adapter into the rack until you hear a click.

4 Be sure the adapter has engaged the rack.

Remove an Adapter

Figure 3.8 Remove an Adapter from a Rack



1. Adapter lock
2. Rack window
3. Push up lightly with a finger

1 To disengage the lock, push the adapter lock lightly with a finger from the outside of the rack window.

2 When the upper edge of the adapter comes out from the rack, pull the remainder of the adapter out.

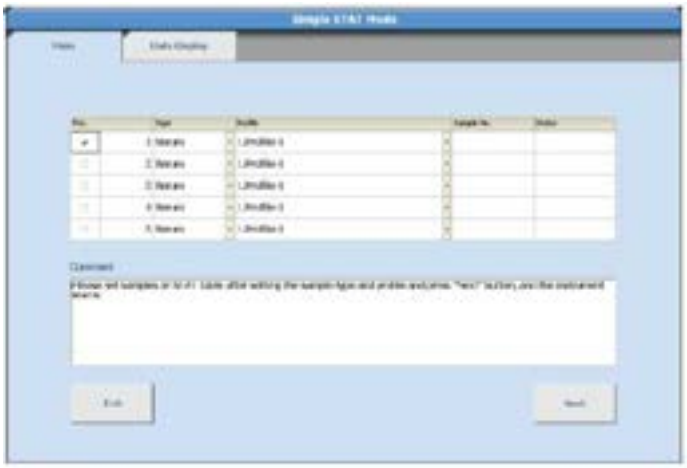
Simple STAT Mode

Simple STAT mode is a STAT analysis mode that allows you to process a maximum of 5 samples at a time. Simple STAT mode is ideal for operators with limited analyzer experience.

Starting and Ending Simple STAT Mode

1 To start Simple STAT mode, select **Home > Simple STAT Mode > Main**.

Figure 3.9 Simple STAT Mode: Main Tab



2 To exit Simple STAT mode, select **Exit**. The system closes the Simple STAT Mode dialog, and displays the Home screen.

Analysis in Simple STAT Mode

1 Select **Pos.** 1 through 5 for the position to place a maximum of five samples on the STAT table.

2 In **Type**, select the sample type.

3 In **Profile**, select the profile.

4 Open the STAT cover and place all of the samples in the correct position on the STAT table according to the displayed position number.

5 Close the STAT cover.

6 Select **Next**. The system starts automatically.

7 Select the **Data Display** tab. The system displays the analysis results. When the system completes results, the results print.

8 Select the **Main** tab.
When the system completes analysis, the system displays a message prompting for sample removal.

9 Remove all samples, close the cover, and then select **Next**.
The system confirms that you have removed all samples, and that Simple STAT mode analysis is complete.

CHAPTER 4

System Monitoring and Results

Reagent Management

Read the Master Curve

This function reads the 2D bar code of the AU reagent with the hand scanner (option) to read the master curve information.

If there is no master curve information, the comment `No Master Curve` is displayed in the Comment column in **Reagent Management > Details**.

This function requires the hand scanner (option). Contact Beckman Coulter for the hand scanner.

1 Select **Read Master Curve (F4)** from **Reagent Management > Details**. The Read Master Curve dialog opens.

Figure 4.1 Read Master Curve Dialog

2 Scan the 2D bar code with the hand scanner. The ID is read, and the corresponding test name and reagent lot number are displayed on the dialog.

3 Select **OK** to save the scanned data.

Review and Delete Reagent History

Display the lot number, bottle number, position, and on-board stability for the history of R1 and R2 reagents. If conflicting information is programmed in **Calibration Parameters** (auto calibration and advanced calibration for the same test), it can be necessary to delete the reagent history for that bottle of reagent.

1 Select **Home > Reagent Management > Details**, and then select **Reagent History (F6)**.

Figure 4.2 Reagent History Dialog

2 Select the test to display from **Test Name**.

NOTE

For sample blank tests (total and direct bilirubin), use the arrow buttons to change the display between the color and blank reagent. For HbA1c%, use the arrow buttons to change the display between HbA1c and T-Hb.

A list of the previous lot numbers and bottle numbers is displayed. The most current bottle data appears on the first line and includes the R1/R2 reagent position and remaining on-board stability.

3 To delete the combination, select **All Delete** to delete all information for the test, and **Delete** to delete the line of information at the cursor. The Reagent History dialog opens.

4 Select **OK**. Selected information is deleted.

5 Select **Close** to close the dialog.

Recovering from a Bottle Position Error

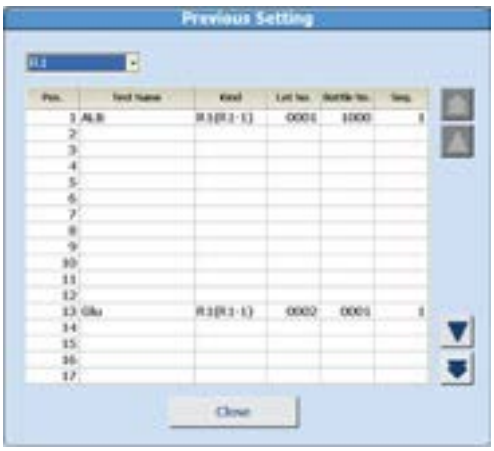
NOTE

After a bottle position error occurs, check the reagent bottle status from the previous reagent check. **Previous Setting (F7)** is only accessible in *Pause* mode.

The system displays `Bottle Set Miss` and continues analysis. Select **Pause** to move the system to *Pause*.

1 Select **Home > Reagent Management > Details**, and then select **Previous Setting (F7)**.

Figure 4.3 Previous Setting Dialog



2 Select **R1** or **R2**. Reagent information is displayed.

3 Confirm the information, and select **Close**.

Initialize Onboard Stability

This function initializes the reagent on-board stability. It is only available for reagents in fixed positions. A Lot No. and Bottle No. (SN) must be entered before the Initialize Onboard Stability function is operational.

Select **Home > Reagent Management > Details > Initialize Onboard Stability** when replacing reagents in fixed positions to update the onboard stability.

Reagent Inventory

Reagent volume required for each test by the day of the week can be calculated from data obtained from the analyzer (Auto), or a value can be entered for each test and day of the week (Manual).

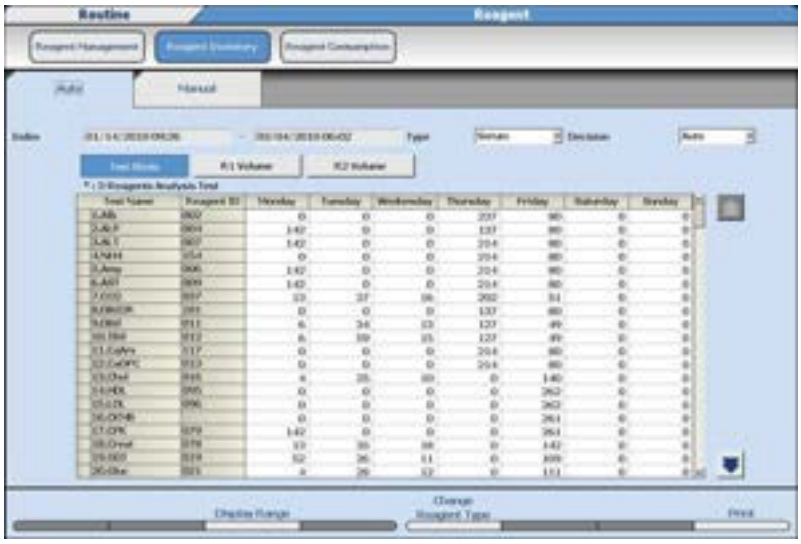
Reagent Inventory displays the number of tests used each day of the week for each sample type within the period set by the index range. Use **Reagent Inventory** to determine how much reagent should be on-board for each day of the week.

Reagent Management > Main displays tests below the required volume for the day of the week in green. The indicator bar displays the volume based on the Margin percentage calculation.

Auto Calculation of Reagent Inventory

1 Select **Home > Reagent Management > Reagent Inventory > Auto**.

Figure 4.4 Reagent Inventory: Auto Tab



Auto calculations can be entered one day in advance.

Table 4.1 Auto Tab Description

Option	Description
Display Range (F3)	Set the starting and ending indexes to calculate the reagent usage.
Change Reagent Type (F5)	Changes the display from R1 -1 to R1-2 reagent. Only available when **R1 Volume** is selected.

2 Select the sample type from **Type**.

3 Select **Display Range (F3)**. The Display Range dialog opens.

Figure 4.5 Display Range Dialog

4 Select the start index and the end index.

5 Select **OK**. The number of tests selected within index range is displayed on the list.

6 Select **R1 Volume** or **R2 Volume**. The reagent consumption is automatically calculated based on an actual result and then displayed on the list by mL.

The reagent consumption is calculated by the following formula:

Actual result x (the amount of reagent dispensing + the amount of surplus dispensing)

7 Select **Auto** from **Decision**. The calculated reagent consumption is set as the required reagent volume indicator in **Reagent Management**.

Manual Calculation of Reagent Inventory

1. Select **Home > Reagent Management > Reagent Inventory > Manual**.
2. Select **Edit (F1)**.
3. Select the sample type from **Type**.
4. Enter the number of tests run for each test for each day of the week.
5. Confirm that the information is correct, and then select **Confirm (F1)**.
6. Select **R1 Volume** or **R2 Volume**. The reagent consumption input is automatically calculated based on entered test numbers and then displayed on the list by mL.
7. Select **Reagent Inventory > Auto**.
8. Select **Manual** from **Decision**. The test count entered for reagent consumption is set as the required reagent volume indicator in **Reagent Management**.

Reagent Consumption

Reagent Consumption displays the amount of reagent used for each test programmed on the analyzer. Set a range of indexes to display the reagent consumption used for analysis for each test by sample type.

1. Select **Home > Reagent Management > Reagent Consumption**.

Figure 4.6 Reagent Consumption Screen

1. Test Shots
2. R1 Volume
3. R2 Volume
4. Test Total
5. Shot Total

Reagent Consumption defaults to display Shot Total. The Shot Total is the cumulative number of tests run on the analyzer from the installation of the analyzer.

2 Select the sample type from **Type**.

3 Select **Display Range (F3)**.

4 Select the **Start Index** and the **End Index**.

5 Select **OK**. The number of cumulative tests is displayed.

Check reagent consumption by samples measured and reagent dispense

1 Select **Test Shots** after setting the index range and sample type. The number of actual reagent dispenses, including repeat tests and re-analyzed tests displays for each test and sample type. The number of reagent dispenses displays for Routine, Emergency, STAT, Repeat, Reagent Blank, Calibration, and QC. The number of dispenses for ISE measurement displays as the number of ISE samples.

2 Select **R1 Volume** or **R2 Volume**.

The volume in mL of reagent dispensed for each test and sample type displays.

The reagent consumption is calculated by the following formula:

Actual analysis result × (the amount of reagent dispensing + the amount of surplus dispensing)

3 Select **Test Total** after setting the index range and sample type. The number of analyzed tests not including repeat tests and re-analyzed tests displays for each test and sample type. The number of tests displays for Routine, Emergency, STAT, Repeat, Reagent Blank, Calibration, and QC. The number of dispenses for ISE measurement displays as the number of ISE tests (Na, K, and Cl).

Save reagent consumption data

1 Select **Report (F7)**.

2 Select **FD**, **CD-R**, or **External Memory Stick**.

3 Select the starting and ending index to save data from **Start Index** and **End Index**.

4 Select **OK**. The reagent consumption data is saved as a csv file.

Display Reaction Monitor

The Reaction Monitor screen displays sample information, reagent information, specific test parameters, reaction data, and analyzer components used for analysis for reagent

blank, calibration, QC, and samples. The Reaction Monitor screen can be used for checking data or troubleshooting.

- A maximum of 100,000 samples, or 10,000 samples per index can be stored on the hard drive.
- A maximum of 200,000 tests can be displayed on the Reaction Monitor screen.

1 Select **Menu List > Routine > Data Monitor > Reaction Monitor > Main**.

Figure 4.7 Reaction Monitor: Main Tab

2 Enter the search parameters for the data to display according to the following table.

Table 4.2 Main Tab Description

Item	Contents	Input Notes
Index	Index	All available indexes are available to select, from the newest index to the oldest.
Test Name	Test Name	Calculated tests are not available to be selected.
Cuvette No.	1 to 165, or *	Specify the cuvette number used for analysis. Enter an asterisk when no cuvette is specified to view each cuvette.
Preprocess Cuvette No.	1 to 165, or *	Specify the cuvette number used for pre-processing. Enter an asterisk when no cuvette is specified to view each cuvette.
Mix Bar No.	1 to 3, or *	Specify the mix bar for R1 (R11), Sample, R2 (R21), and Preprocess used for analysis. Enter an asterisk when no mix bar is specified to view each mix bar.

Table 4.2 Main Tab Description (Continued)

Item	Contents	Input Notes
Normal, Repeat, Cal/QC	Enter the search parameters for sample number and sample ID for each type.	Sample kinds and types not processed are gray and inaccessible.
— Sample Kind	Select the sample kind and type to search.	Sample kinds and types not processed are gray and inaccessible.
— Search Sample No.	Leave the asterisk to search all the sample numbers processed, or enter a specific sample number or range of sample numbers to search.	The starting and ending sample numbers processed display under the Search Sample No. column.
— Search Sample ID — Control/ Calibrator ID	Leave the asterisk to search all sample IDs processed, or enter a specific sample ID to search.	An asterisk displays under the Search Sample ID column.
	Select: — **None** — **Partial Match** — **Complete Match**	— **None**: Not using sample ID as the search criteria. — **Partial Match**: Retrieve the sample(s) with a partial sample ID match. — **Complete Match**: Retrieve the sample with a complete sample ID match.
— Counts	Select the Counts for Calibration and RB replicate 1 to 4.	Available only for Calibration and RB (reagent blank) data. The replicate number 1 to 4 is programmed in **Calibration Specific**.
— Sequence	Select the reagent bottle Sequence 1 to 5 for Calibration, QC, and RB.	Available only for Calibration, QC, and RB (reagent blank) data. Sequence is the serial reagent bottle number 1 to 5 for each test. When nothing has been checked, data matching the specified Sample No. and bottle sequence number is displayed.

The following additional search criteria must be selected after Patient, Repeat Run, or RB/CAL/QC is selected:

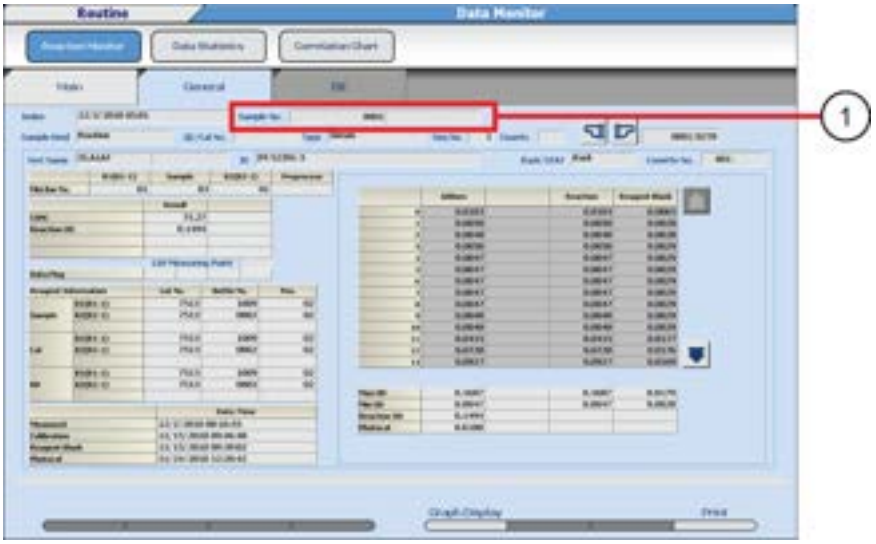
— Under the Sample Kind column, select the sample kind and type to search. Sample kinds and types not processed are gray and inaccessible.
— The starting and ending sample numbers processed display under the Search Sample No. column. Leave the asterisk to search all the sample numbers processed, or enter a specific sample number or range of sample numbers to search.
— An asterisk displays under the Search Sample ID column. Leave the asterisk to search all sample IDs processed, or enter a specific sample ID to search.

— If RB/CAL/QC is selected, the Counts (replicates) and Sequence (bottle sequence number 1-5) can be specified to search.

3 Select the **General** tab. The search starts. If there is data based on the search criteria, the General tab displays with the first sample found. If no data is found based on the search criteria, a message `No Data Found` displays. Select **OK** to return to the Main tab.

4 Review the data in the General tab.

Figure 4.8 Reaction Monitor: General Tab



1. Sample No.

— Left column: The sample number of the currently displayed reaction data is displayed.
— Right column: If the sample number is from the original run, the display is blank. If the sample number is from the repeat run, the original sample number displays.

Table 4.3 Sample No. Description

	Sample No. (left column)	Sample No. (right column)
Original run data display	Original Sample No.	Blank display
Repeat run data display	Repeat Sample No.	Original Sample No.

Table 4.4 Sample Data Prefix

Type		Normal Run	Repeat Run
Routine	Serum	(None)	H
	Urine	U	HU
	Other-1	X	HX
	Other-2	Y	HY
	Whole Blood	W	HW

Table 4.4 Sample Data Prefix (Continued)

Type		Normal Run	Repeat Run
Emergency sample	Serum	E	HE
	Urine	UE	HUE
	Other-1	XE	HXE
	Other-2	YE	HYE
	Whole Blood	WE	HWE
STAT sample	Serum	P	HP
	Urine	UP	HUP
	Other-1	XP	HXP
	Other-2	YP	HYP
QC		Q	
CAL		A	
RB		R	

5 Select **Graph Display (F5)**.

The display changes to graph display. The primary wavelength, secondary wavelength, and calculation of the reaction absorbance are displayed color-coded on the graph.

Figure 4.9 General Tab: Graph Display (F5)

NOTE

When the total dispensing volume is below the minimum test liquid quantity, the graph is displayed as a dotted line.

The minimum test volume:

120 µL (for all markets except Japan)
90 µL (for Japan only)

— In case of (R1[R1-1] dispensing volume + R1[R1-1] diluent quantity) < minimum test liquid quantity, the straight line between P0 and P1 is displayed as a dotted line.
— In case of (R1[R1-1] dispensing volume + R1[R1-1] diluent quantity) + (sample dispensing volume + sample diluent quantity) < minimum test liquid quantity, the straight lines between P0 and P10 are displayed as dotted lines.

6 Select **Scale Change (F6)** to change the absorbance scale of the graph. The Scale Change dialog opens.

7 Enter the lower limit value and the upper limit value and select **Manual**. The setting range for the lower limit value and the upper limit value is from -2.000 to 3.000 (in units of 0.001). When **Auto** is selected, the scale is set automatically.

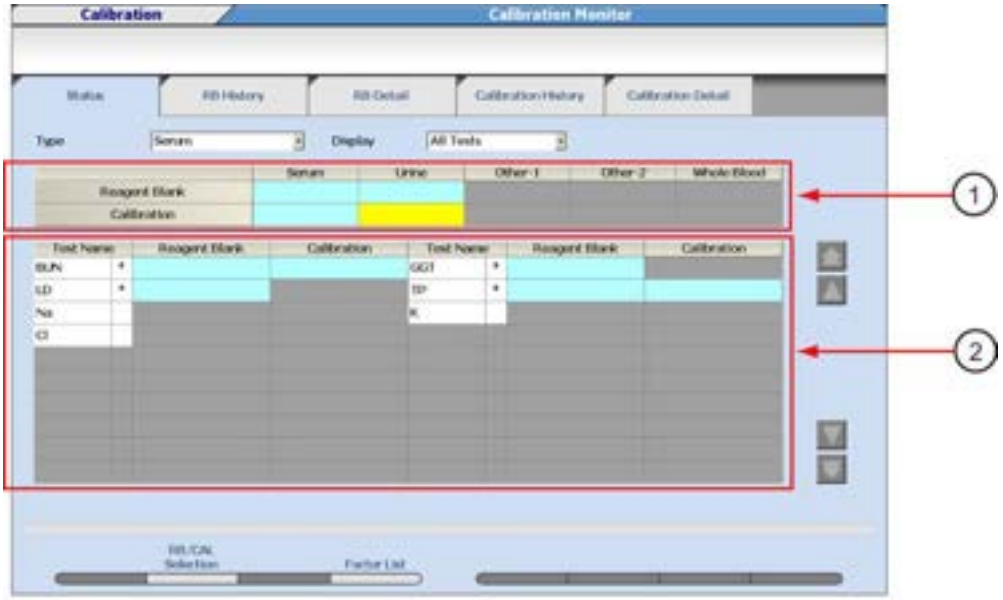
Monitor the Reagent Blank and Calibration

Use the following procedure to monitor and confirm reagent blank and calibration results.

Reagent Blank and Calibration Status

1 Select **Menu List > Calibration > Calibration Monitor > Status**.

Figure 4.10 Calibration Monitor: Status Tab



1. Sample Type list
2. Test list

Table 4.5 Sample Type List

Color	Status
Orange	No calibration data, Failed, or Expired.
White	Reagents Unchecked and judgement is impossible.
Gray	The sample type is not available according to **Type**.
Blue	No errors.
Yellow	Calibration Expires Soon.

The Test List is a list of analysis tests registered for each group. The asterisk by Test Name indicates Advanced Calibration is programmed for the test.

Table 4.6 Test List

Display	Color	Status
No data	Orange	Bottles without calibration data exist.
Failed		Bottles with failed calibration exist.
Expired		Bottles with expired calibration exist.
Expired soon	Yellow	Bottles with calibration data that expires soon exist.
-	Blue	No errors.
-	White	Reagent Unchecked and judgement is impossible.

2 Select the sample type from **Type**. The present reagent blanks and calibration status are displayed as a list. Tests displaying an asterisk are tests with Advanced Calibration programmed.

3 Select **All Tests** or **Tests with Error** from **Display**.

— **All Tests** - Displays all the test data for the Group.
— **Tests With Error** - Displays data with an error in calibration or reagent blanks.

4 Select the **Reagent Blank** column or **Calibration** column of a test to view the RB History tab or Calibration History tab. The most recent reagent blank or calibration data displays.

Select the date on the x-axis of the graph to view the corresponding calibration data.

5 Select the **RB Detail** tab to display and print the detailed reagent blank data for each test. Select the **Calibration Detail** tab to display and print the detailed calibration data and graphs for each test.

6 To view the individual status on multiple bottles, select **RB/CAL Selection (F2)**. The RB/CAL Status dialog opens.

Figure 4.11 RB/CAL Status Dialog

7 Select the **Reagent Blank** column or **Calibration** column to view the RB Detail tab or Calibration Detail tab. The display changes to the respective RB Detail tab or Calibration Detail tab, and the detailed information appears. Select the **Status** tab to return to reagent blank and calibration status.

8 Select **Factor List (F4)**. The Factor List dialog opens. Factor A for tests where the interpolation formula for the calibration curve is the type Y = AX + B is displayed.

9 After confirmation of the factor, select **Close**. The Factor List dialog closes.

Review Reagent Blank and Calibration History

Review Reagent Blank History

1 Select **Menu List > Calibration > Calibration Monitor**. From the Status tab, select the **Reagent Blank** column of the test name to go to the RB History tab.

Figure 4.12 Calibration Monitor: RB History Tab

— P0: Measuring point 0.

— Px: The read point programmed in the Measuring Point-1 First field in **Specific Test Parameters**.
— Py: The read point programmed in the Measuring Point-1 Last field in **Specific Test Parameters**. When the Measuring Point-1 First field is programmed to 0, this field is blank (not accessible).

2 View a graph of the OD of the reagent blank. The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. The vertical line indicates a new lot number or new bottle number of reagent when Advanced Calibration is programmed to Bottle/Bottle.

3 Select the test to display from **Test Name**.

Review Calibration History

1 Select **Menu List > Calibration > Calibration Monitor**. From the Status tab, select the **Calibration** column of the test name to go to the Calibration History tab.

Figure 4.13 Calibration Monitor: Calibration History Tab

2 View the calibration OD on a graph. The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. The vertical line indicates a new lot number or new bottle number of reagent when Advanced Calibration is programmed to Bottle/Bottle.

3 Select the test to display from **Test Name**.

Review Reagent Blank and Calibration Detailed Data

Review RB Detail

1 Select **Menu List > Calibration > Calibration Monitor**. From the Status tab, select **RB/CAL Selection (F2)**, and then select the **Reagent Blank** column of the test name to go to the RB Detail tab.

Figure 4.14 Calibration Monitor: RB Detail Tab

2 View detailed reagent blank data information.

3 Select the test to display from **Test Name**.

Print Reagent Blank Data

1 From the RB Detail tab, select **Print (F8)**.

2 The system opens the Print dialog with options.

- **Recent/History:** Recent data or History (maximum of 100 points)
- **Data Options:** Result (OD for all read points) or Representation (OD for P0, Px and Py. Px and Py are the read points of the test)
- **Test Print Options:** Display Test or All Tests

3 Select **OK** to print.

Review Calibration Detail

1 Select **Menu List > Calibration > Calibration Monitor**. From the Status tab, select **RB/CAL Selection (F2)**, and then select the **Calibration** column of the test name to go to the Calibration Detail tab.

Figure 4.15 Calibration Monitor: Calibration Detail Tab

2 View detailed calibration data information.

3 In **Test Name**, select the test to display.

Print Calibration Data

1 From the Calibration Detail tab, select **Print (F8)**.

2 The system opens the Print dialog with options.

- **Recent/History:** Recent data or History (maximum of 100 points)
- **Test Print Options:** Display Test or All Tests
- **Factor:** Without Factor or With Factor

3 Select **OK** to print.

Display Data History

Display Data History and Add a Comment are common to the RB History, RB Detail, Calibration History, and Calibration Detail tabs. Change the Graph Scale is common to the RB History, Calibration History, and Calibration Detail tabs.

1 Select **Data Select (F3)** to display a history of the R1 and R2 lot number and bottle number.

Figure 4.16 Data Select Dialog

2 Select the reagent blank data to display from the Date column, then select **OK**.

NOTE

Reagent Blank and Calibration history data can also be displayed by selecting a date and time from **Date/Time** in the RB History tab or Calibration History tab, or by selecting the date on the x-axis of the graph.

Add a Comment

Master Comments are pre-programmed comments that can be selected to avoid retyping common comments. Program master comments using **System** > **Comment Master**. For more information, refer to Comment Masters Menu.

You can add master comments to RB and Calibration data.

Comments created in RB History or RB Details tabs display in both tabs. Comments created in Calibration History and Calibration Details tabs display in both tabs.

1 Select **Comment (F5)**. The Comment dialog opens.

Figure 4.17 Comment Dialog

2 Select **Comment**. The dialog to select a master comment appears.

3 Select the comment to be set.

4 Select **OK**. The dialog is closed and the selected comment is displayed in the dialog. Edit the comment if necessary.

5 If master comments are not programmed, enter a comment.

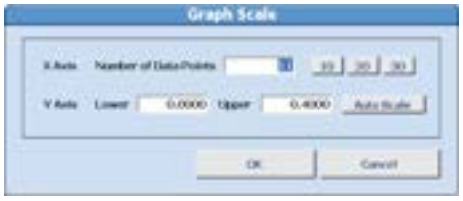
6 Select **OK** to register the comment. The dialog is closed.

Change the Graph Scale

The graph display size can be changed.

1 Select **Graph Scale (F7)**. The Graph Scale dialog opens.

Figure 4.18 Graph Scale Dialog



2 Select the **10**, **20**, or **30** button to enter the Number of Data Points, or enter a number.

3 For the Y Axis, set the **Lower** limit value and **Upper** limit value.

When **Auto Scale** is selected, the upper limit value and the lower limit value are automatically set, and the scale calculation is displayed.

4 Select **OK**. The graph is redrawn with the set scale.

Lot Calibration Option

This option is programmed in **Parameters** > **Calibration Parameters** > **Calibration Specific**. It is functional if a check is placed by Lot Calibration and Advanced Calibration is set to Lot/Lot. The option affects the reagent blank and calibration stability when a second bottle of reagent is placed on the system. When Lot Calibration is checked, a maximum of two bottles of reagent can be onboard instead of five.

If checked, when the second bottle of reagent is placed on the system, the calibration factor from the first bottle of reagent (base factor) is used for the second bottle of reagent. The reagent blank and calibration stability for the first bottle continues to be tracked, and the reagent blank and calibration stability for the second bottle is set to the programmed stability in **Calibration Specific**.

If unchecked, when the second bottle of reagent is placed on the system, the reagent blank and calibration stability is tracked at the first bottle's remaining stability period for both bottles. In the **Calibration Monitor > Calibration Detail** tab, the calibration factor can be selected for Base or Analysis data.

1 Select **Calibration Detail**, and then select **Lot to Lot Calibration (F1)**.

Figure 4.19 Lot to Lot Calibration Dialog

Calibration data status is displayed in the Comment column.

Table 4.7 Lot to Lot Calibration Dialog Description

Comment	Description
Base	The calibration factor from the first bottle of reagent is used for the second bottle of reagent.
Analysis	The calibration factor is obtained from calibration analysis.
Base (Copy)	The calibration data is copied from the Base data.
Unuse	Calibration data has been deleted from the Base (Copy) data, and selection is impossible.

2 Select the calibration data to be used.

3 Select **OK** to save the settings. The Lot to Lot Calibration dialog is closed.

Calibration Verification

Calibration verification should use material appropriate for the testing system and when possible traceable to a reference method or material of known value with stated acceptable variations.

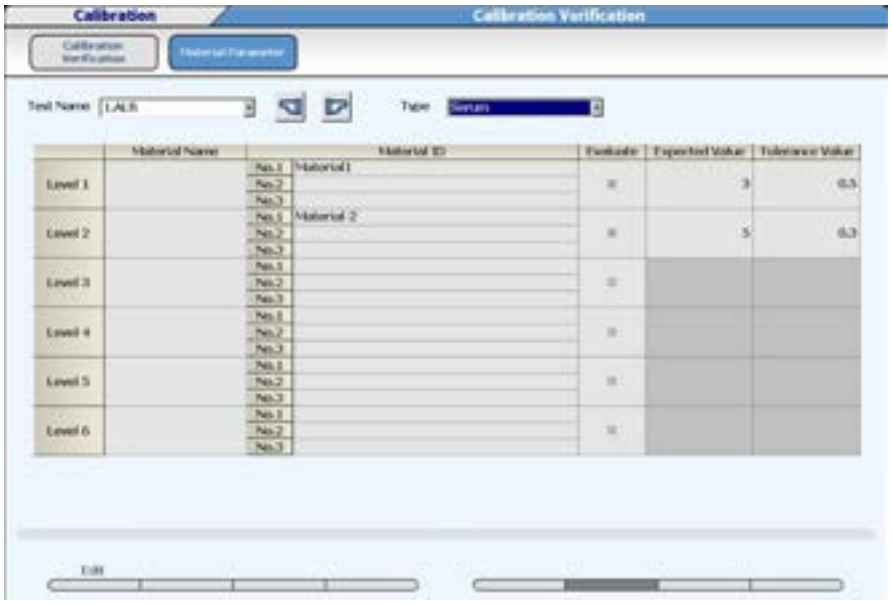
Program material parameters, then perform analysis of the calibration verification material. View a graph of the actual versus expected values. Three replicates of each test level (a maximum of 6 levels per test) can be plotted on the graph.

Enter Material Parameters

To enter information concerning the standard material:

1 Select **Menu List > Calibration > Calibration Verification > Material Parameters**.

Figure 4.20 Calibration Verification: Material Parameter Screen



2 Select **Edit (F1)**. The screen changes to edit mode.

3 Select the test name from **Test Name**.

4 Select the sample type from **Type**.

5 Enter the **Material Name** for each level. Enter up to 8 characters.

6 If sample ID is in use, enter the sample bar code number (maximum of 20 characters) in **Material ID**. Up to three sample IDs can be assigned to each level for three replicates.

7 Select **Evaluate** to include the material for calibration verification. Clear **Evaluate** to exclude the registered material.

8 Enter the **Expected Value** and **Tolerance Value** (refer to the calibration verification material package insert for specifications).

9 Select **Confirm (F1)** to save the settings.

Order (Requisition) and Sample Analysis

The following procedure describes how to process the calibration verification material.

1 Select **Home > Rack Requisition Sample > Sample > Test Requisition**.

2 For **Sample Kind**, select **Switch** and then select **Routine** or **Emergency** samples.

— Routine: Analysis in a white rack
— Emergency: Analysis in a red rack

3 Select the sample type from **Type**.

4 Select **Start Entry (F1)**.

5 For **Sample ID**, enter the sample bar code number.

6 Select the tests to be evaluated for the calibration verification.

7 Select **Batch Entry (F3)**.

8 Select the **Number of Samples** option and enter the number of samples to be processed.

9 Select **OK**.
The sample IDs will automatically increment by one for each sample in the batch.

10 Select **Exit (F2)**.

11 Select **Pending List (F4)** to view a list of samples requisitioned.

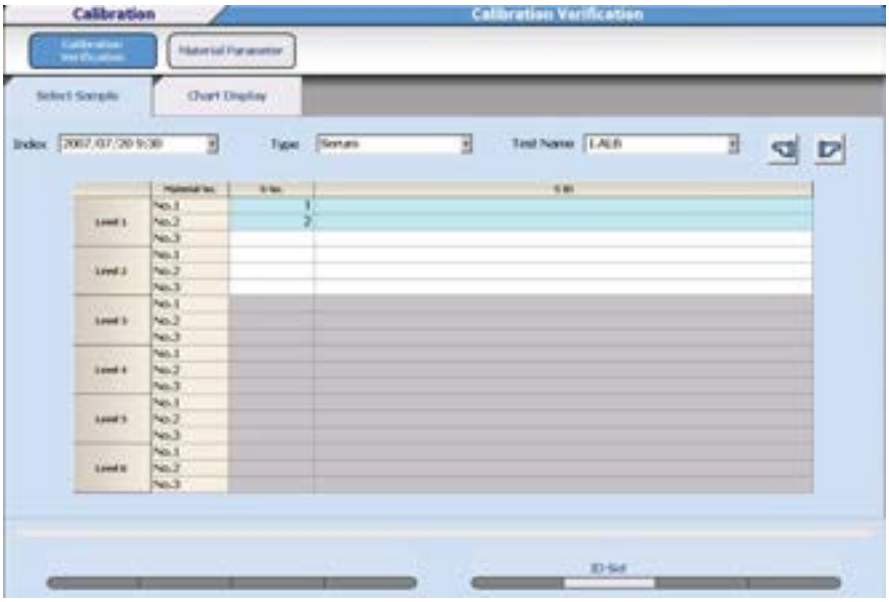
12 Start sample analysis. Refer to the AU680 Instructions for Use.

Verify Calibration

Display the expected value and allowable tolerance for each level using vertical lines. If the measurement value of each material is in this range, judge the calibration curve to be satisfactory.

1 Select **Menu List > Calibration > Calibration Verification > Calibration Verification > Select Sample**.

Figure 4.21 Calibration Verification: Select Sample Tab



2 Select the index from **Index**.

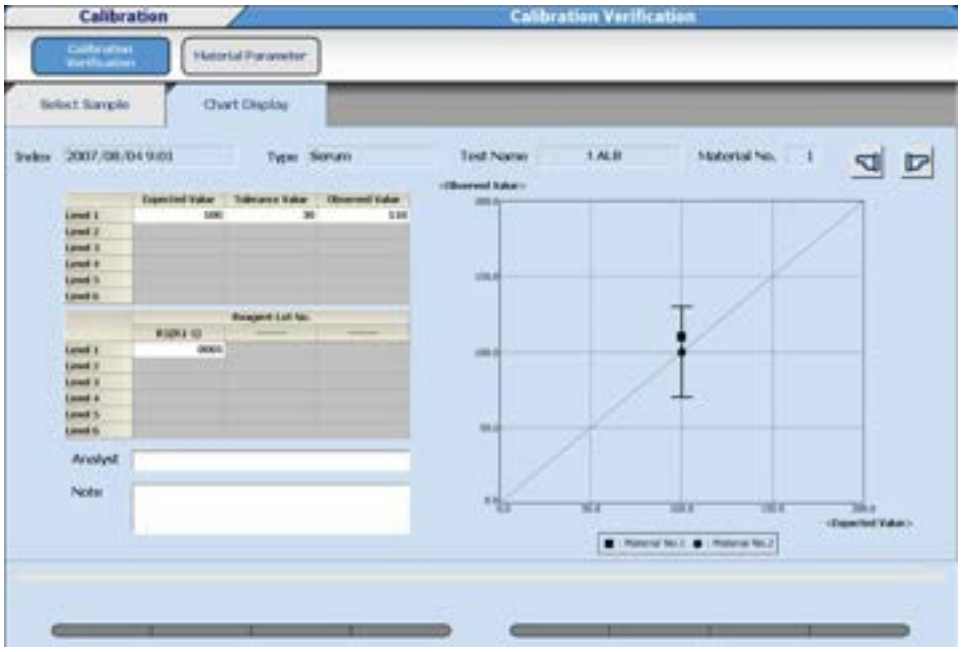
3 Select the sample type from **Type**.

4 Select the test name from **Test Name**.

5 Enter the sample numbers processed for each **Level** and **Material No.** in **S No.** If barcode analysis was used to process the material, enter the sample ID number for each **Level** and **Material No.**, or select **ID Set (F6)** to use the sample ID numbers programmed in **Material Parameters**.

6 Select the **Chart Display** tab to display a graph of the observed versus the expected values. All specified levels are displayed on the graph.

Figure 4.22 Calibration Verification: Chart Display Tab



7 Confirm the data. The graph displays the tolerance range with vertical lines centered on the expected value. Acceptable results should appear within the vertical lines. A calibration curve is drawn through the expected values. For Analyst, the name of the person performing the calibration verification can be entered (up to 20 characters). For Note, a comment can be entered (up to 100 characters).

A notification dialog opens if data cannot be found. Select **OK** to return to **Select Sample**.

Monitor QC

The following are options for monitoring QC results:

- Monitor the QC Using the Daily Variation Chart
- Monitor the QC Using the Day-to-Day Variation Chart

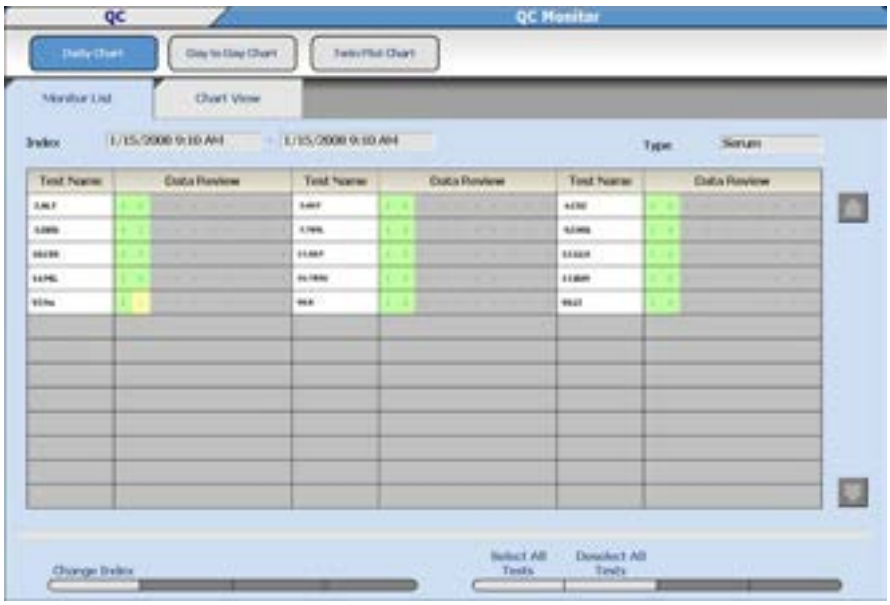
- Monitor the QC Using the Twin Plot Chart

Monitor the QC Using the Daily Variation Chart

QC results can be reviewed by plotting the individual QC points from one index or a range of indexes on a single chart. Always review the daily variation chart after performing daily QC analysis.

1 Select **Menu List > QC > QC Monitor > Daily Chart > Monitor List**.

Figure 4.23 Daily Chart: Monitor List Tab



Data Review Column colors:

— Green: Normal data
— Yellow: Data outside the range of the Single Check Level programmed in **QC Specific**
— Orange: Abnormal data (data not included in the QC statistical values)

2 Select **Change Index (F1)**. The Change Index dialog opens. Select the index or index range to display from **Start Index** and **End Index**.

3 Select the sample type from **Type**.

4 Select **Data Search** to search for QC data based on the index and sample type selected.

5 Select the tests to display.

NOTE

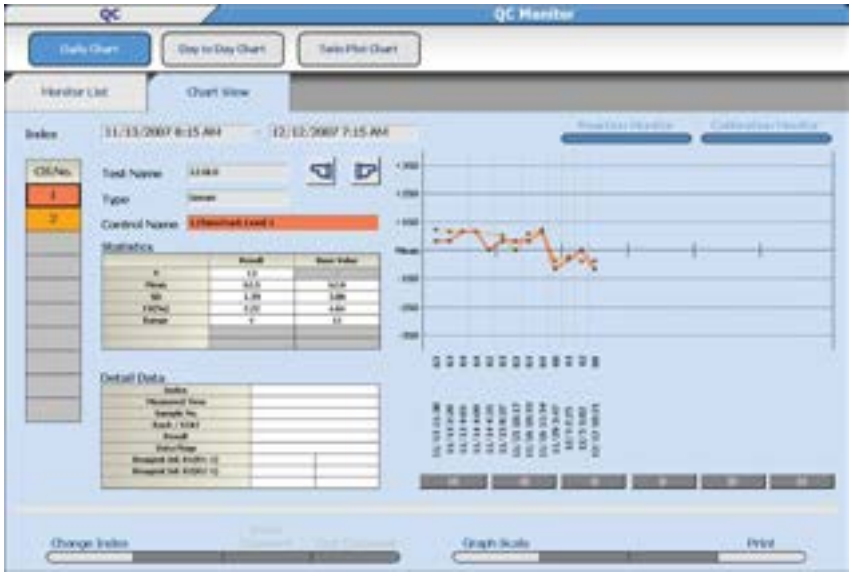
When **Select All Tests (F5)** is selected, all displayed test names are selected.

When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

6 Select the **Chart View** tab. The Daily Variation chart is displayed.

A chart is displayed for each test. Each control material assigned to the test is displayed in a different color listed under **Ctl No.** Select the control number to highlight the control on the graph and display the control number **Detail Data**. When ± 3SD from the mean value is exceeded, the point is outside the display range.

Figure 4.24 Daily Chart: Chart View Tab



- **Control Name** - Select a control number assigned to the test under **Ctl No.** to display the control on the graph and **Detail Data**.
- **Statistics** - The statistical values for the entire system are displayed.
- **Detail Data** - Select the date and time on the x-axis of the graph to display the detailed data for that control.
- **Graph Scale (F5)** - When selected, the number of data to display on the X-axis can be selected as 10, 20, or 30. The display of the Y-axis cannot be changed.

7 Select or .

The QC daily variation chart for the preceding and following test names is displayed.

8 Select **Reaction Monitor**. The reaction monitor for the displayed data is displayed.

9 Select **Back** from Reaction Monitor. The display returns to the Chart View tab.

10 Select **Calibration Monitor**. The calibration monitor for the displayed test is displayed.

11 Select **Back** from **Calibration Monitor > Calibration History**. The display returns to the Chart View tab.

12 Select **Print (F8)**. The Print dialog opens.

13 Select the List Type options (Statistics, Detail Data, Graph, and with Comments) to print.

Select the Output Data (Current Test or All Test) to print.

14 Select **OK**. Printing starts.

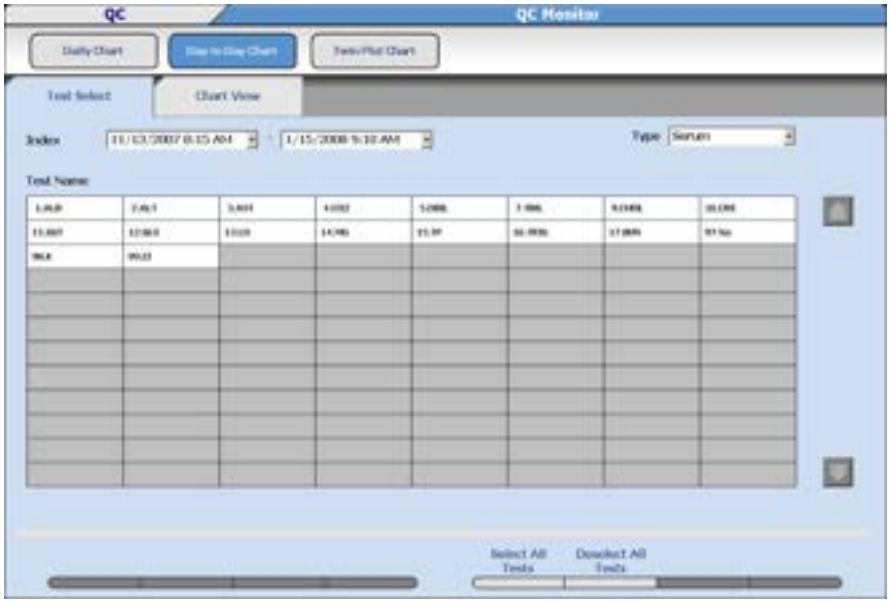
Monitor the QC Using the Day-to-Day Variation Chart

The day to day variation chart compares QC results by plotting a number of days of QC analysis on a chart that displays the variation. All QC points for a specific control within an index are averaged, then plotted on the day to day chart.

Select the range of indexes to display.

1 Select **Menu List > QC > QC Monitor > Day to Day Chart > Test Select**.

Figure 4.25 Day to Day Chart: Test Select Tab



2 Select the starting and ending index range to display from **Index**.

3 Select the sample type from **Type**.

4 Select the tests to display.

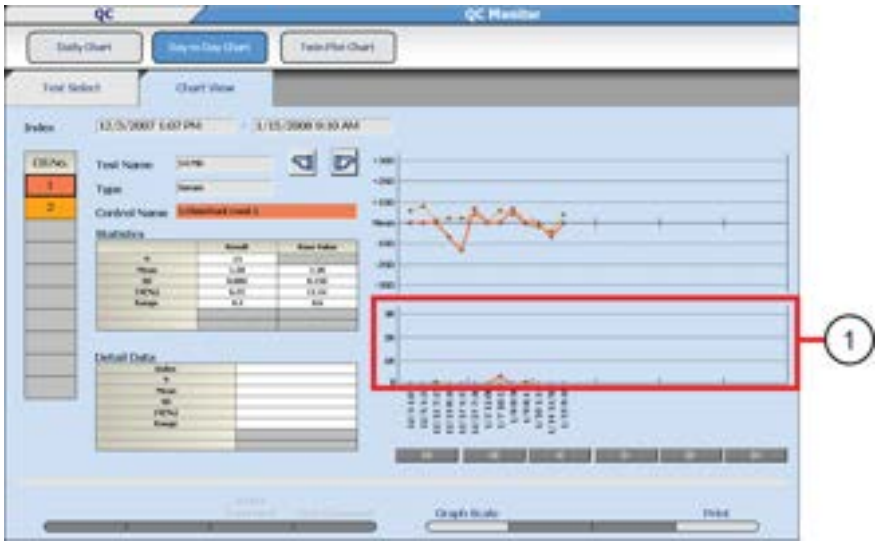
NOTE

When **Select All Tests (F5)** is selected, all displayed test names are selected.

When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

5 Select the **Chart View** tab. The selected day-to-day control chart appears.

Figure 4.26 Day to Day Chart: Chart View Tab



1. Range (R) Graph

— **Control Name** - Select a control number assigned to the test under **Ctl No.** to display the control on the graph and **Detail Data**.
— **Statistics** - The statistical values for the entire system are displayed.
— **Detail Data** - Select the date and time on the x-axis of the graph to display the detailed data for that control.
— **Graph Scale (F5)** - When selected, the number of data to display on the X-axis can be selected as 10, 20, or 30. The display of the Y-axis cannot be changed.
— **Range (R) Graph** - The difference in the range of the QC data for each index. The R value is determined by the Range programmed in **QC Specific**. For example, if 12 is programmed for Range in **QC Specific**, then 1R on the graph has a value of 12 and 2R has a value of 24. The Range Graph is more effective for evaluating precision than accuracy.

6 Select or .

The QC daily variation chart for the preceding and following test names is displayed.

7 Select **Print (F8)**. The Print dialog opens.

8 Select the List Type options (Statistics, Detail Data, Graph, and with Comments) to print.

Select the Output Data (Current Test or All Test) to print.

9 Select **OK**. Printing starts.

Monitor the QC Using the Twin Plot Chart

Use Twin Plot analysis to determine whether a QC variation is caused by the system or is the result of a random error. QC analysis is usually performed using two QC samples:

- A sample in the reference range
- A sample in the pathological range

The twin plot function displays the first QC sample on the x-axis of a 2-dimensional plot and the second QC sample on the y-axis. All points should fall within the 2SD range in the center of the twin plot.

1 Select **Menu List > QC > QC Monitor > Twin Plot Chart > Test Select**.

2 Select the starting and ending index range to display from **Index**.

3 Select the sample type from **Type**.

4 Select the tests to display.

NOTE

When **Select All Tests (F5)** is selected, all displayed test names are selected.

When **Deselect All Tests (F6)** is selected, all selected test names are deselected.

5 Select the **Sample** tab. The system displays QC data by sample number for the range of indexes selected.

Figure 4.27 Twin Plot Chart: Sample Tab

NOTE

As the tests selected with the Test Select tab are displayed together, the causes for fluctuations in regard to temperature and calibrator can be estimated more easily.

Select **Display Test Name** to display test names on the chart.

When a test name is selected, the test name is displayed on the graph highlighted in red.

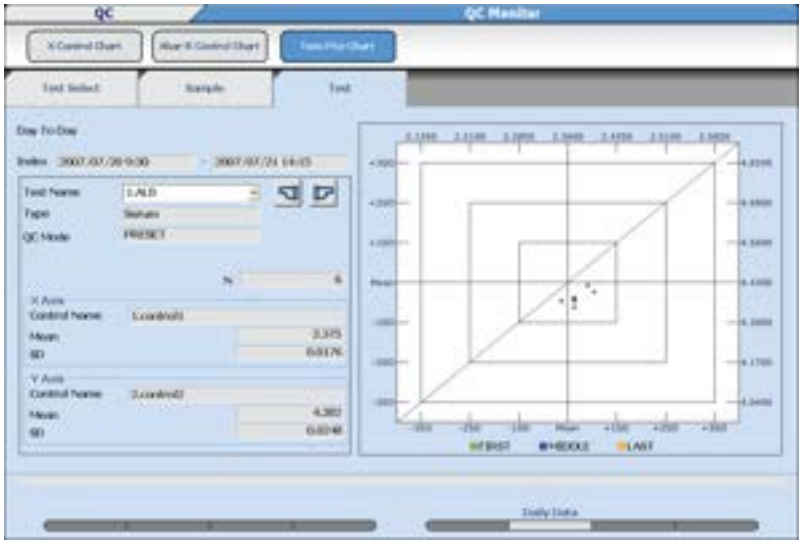
6 Select the QC sample number to view from **QC Sample No.**.

NOTE

When any abnormal condition occurs, refer to the AU680 Instructions for Use.

7 Select the **Test** tab.

Figure 4.28 Twin Plot Chart: Test Tab



The tests selected in the Test Select tab are displayed for each test.

QC data is displayed chronologically, divided into three blocks to review high shifts or other errors.

To display the daily statistical results, select **Daily Data (F6)**.

Add a QC Comment

Master Comments are pre-programmed comments that can be selected to avoid retyping common comments. Program master comments using **System** > **Comment Master**. For more information, refer to Comment Masters Menu.

You can add master comments to QC data.

Comments can be added in the Chart View tab in **Daily Chart** or **Day to Day Chart**. An Index Comment adds the comment by the Index title for all QC in the index. A Test Comment adds the comment by a specific test within the index.

Index Comments

1 Select **Menu List > QC > QC Monitor > Daily Chart** or **Day to Day Chart > Chart View**. Select the date and time below the x-axis of the graph for the comment.

2 Select **Index Comment (F3)**. The QC Comment (Index Common Comment) dialog opens.

Figure 4.29 QC Comment (Index Common Comment) Dialog

3 Enter a comment or select a comment from **Comment**.

4 Select **OK**. The dialog closes. Comments can be viewed by selecting **Index Comment (F3)**, or printed by selecting **Print (F8)** and **With Comments**.

Test Comments

1 Select **Menu List > QC > QC Monitor > Daily Chart** or **Day to Day Chart > Chart View**. Select the date and time below the x-axis of the graph for the comment.

2 Select **Test Comment (F4)**. The QC Comment (Test Comment) dialog opens.

Figure 4.30 QC Comment (Test Comment) Dialog

3 Enter a comment or select a comment from **Comment**.

4 Select **OK**. The dialog closes. Comments can be viewed by selecting **Test Comment (F4)**, or printed by selecting **Print (F8)** and **With Comments**.

Edit Quality Control Data

Analyzed QC data can be searched and edited.

Editing, deleting, or adding a comment can be performed by QC sample number or test.

CAUTION

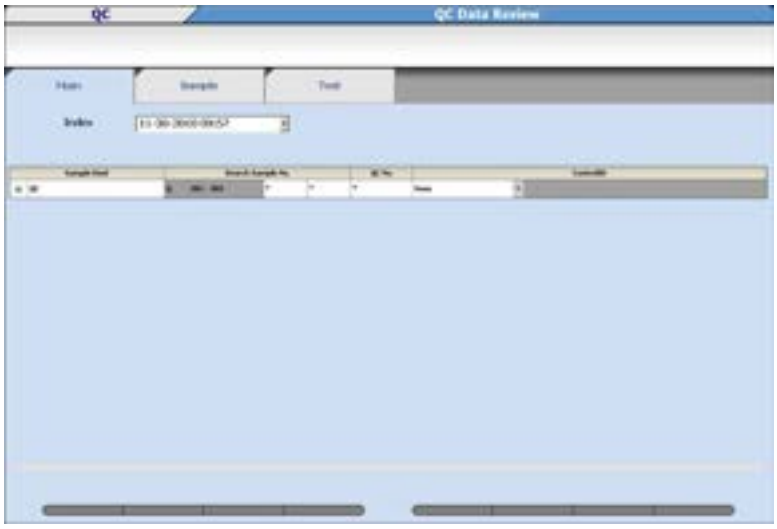
Analyzed QC results can be edited. To prevent an erroneous diagnosis caused by numerous changes to the quality control data, editing should be done according to your laboratory procedure.

NOTE

When the QC analysis data results have been edited, confirm that the edited data falls within the cumulative period. If it falls within the cumulative period, the editing of the contents must be reflected in the cumulative values. To reflect the editing of contents in the cumulative values, update the cumulative values. For more information, refer to QC Specific Screen.

1 Select **Menu List > QC > QC Data Review > Main**.

Figure 4.31 QC Data Review: Main Tab



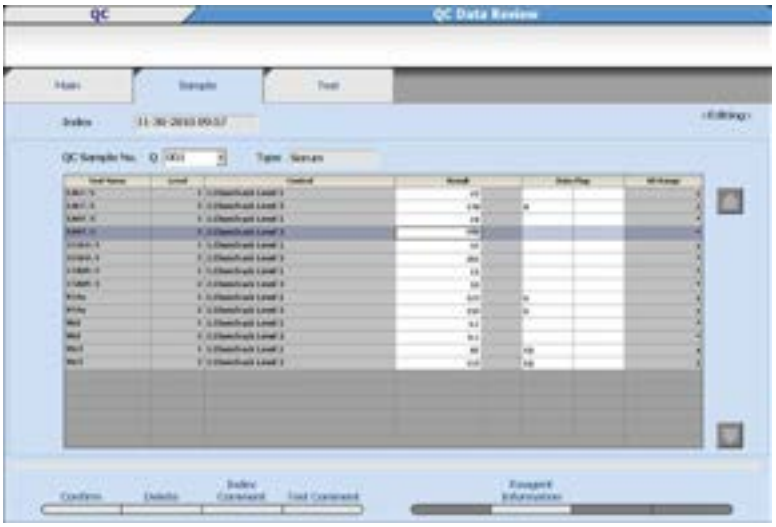
2 Select the index from **Index**.

3 Select **QC** in the Sample Kind column. Set the search range by entering the Search Sample No., the QC No., and the Control ID. The asterisk searches for all data.

4 Select the **Sample** or **Test** tab to display the search results. A message dialog displays if no results are found. Select **OK** to return to the Main tab.

5 Select the **Sample** tab to edit QC by QC sample number.

Figure 4.32 QC Data Review: Sample Tab



a. Select **Edit (F1)**.

b. To edit a test in the sample, select the Result or Data Flag to edit. To delete a test enter a d flag in Data Flag.

c. To delete the entire QC sample (Q001 for example includes all controls in the first QC run), select **Delete (F2)**. A d flag is attached to all tests in the sample. Select **OK** in the Confirmation dialog.

d. To edit a comment, select **Index Comment (F3)** or **Test Comment (F4)**.

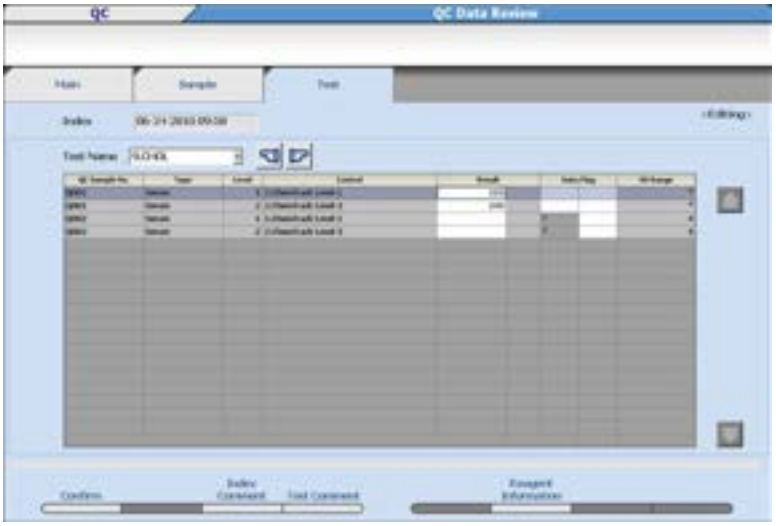
e. Select **Confirm (F1)** to program the QC edits or deletions.

When results have been edited, an e flag is added to the Data Flags. When an e flag has been added, it cannot be deleted. When a d flag is added to the Data Flags, the data is not included in the QC statistic calculations.

---

6 Select the **Test** tab to edit QC by test.

Figure 4.33 QC Data Review: Test Tab



a. Select **Edit (F1)**.

b. Select the test to edit or delete from **Test Name**.

c. Select the Result or Data Flag to edit. To delete a sample enter a d flag in Data Flag.

d. To edit a comment, select **Index Comment (F3)** or **Test Comment (F4)**.

e. Select **Confirm (F1)** to program the QC edits or deletions.

When test results have been edited, an e flag is added to the Data Flags. When an e flag has been added, it cannot be deleted. When a d flag is added to the Data Flags, the data is not included in the QC statistic calculations.

Monitor Repeat Results

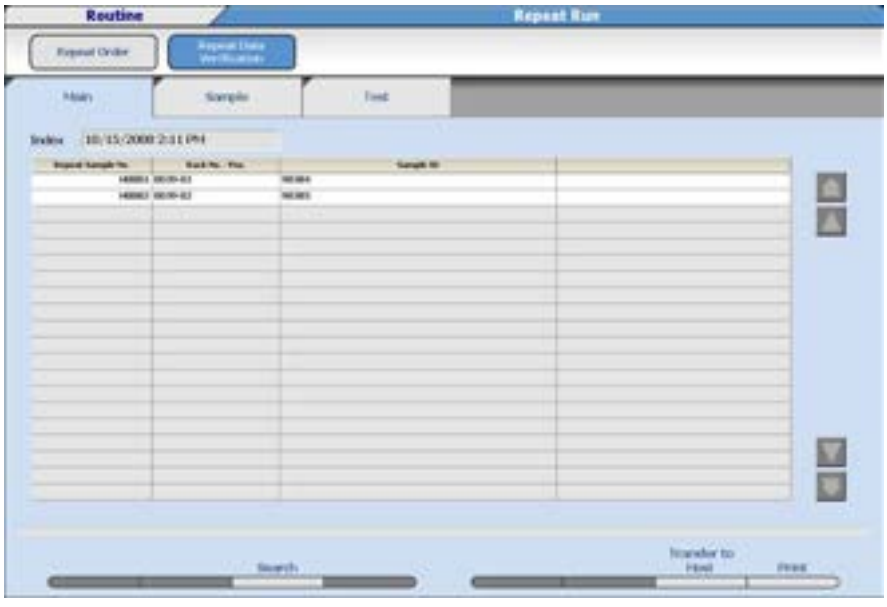
Verify the original and repeat test results. The original result can be automatically overwritten with the repeat result, depending on the programming in **Repeat Common**.

For more information on programming the automatic overwrite option, refer to Repeat Common Screen.

Overwrite the Data

1 Select **Menu List > Routine > Repeat Run > Repeat Data Verification > Main**.

Figure 4.34 Repeat Data Verification: Main Tab



NOTE

The screen displays the current Index and data. Select **OK** if No Data Found displays.

2 Select **Search (F3)** to search for data by an Index, Sample Number(s), Sample ID, or Data Not Transferred to Host. Use the scroll bars to change Sample Kind to Priority STAT or Emergency. Select **OK** to update the contents of the Main tab.

3 Select the **Sample** tab to review original and repeat data by repeat sample number. Select the **Test** tab to review original and repeat data by test.

4 In the Sample tab, select **Sample No.**, then select the tests to overwrite. In the Test tab, select **Test Name**, then the repeat sample numbers to overwrite.

5 Select **Overwritten by Repeat (F5)**. Select **OK** to overwrite data. An S flag is attached to data if the original result is overwritten with the repeat result.

CAUTION

The original data is not available after it is overwritten with repeat data.

Print the Overwritten Data

1 Select **Menu List > Routine > Repeat Run > Repeat Data Verification > Main**.

2 Select **Print (F8)**. The Print dialog opens.

3 Select the list format from **List Format**.

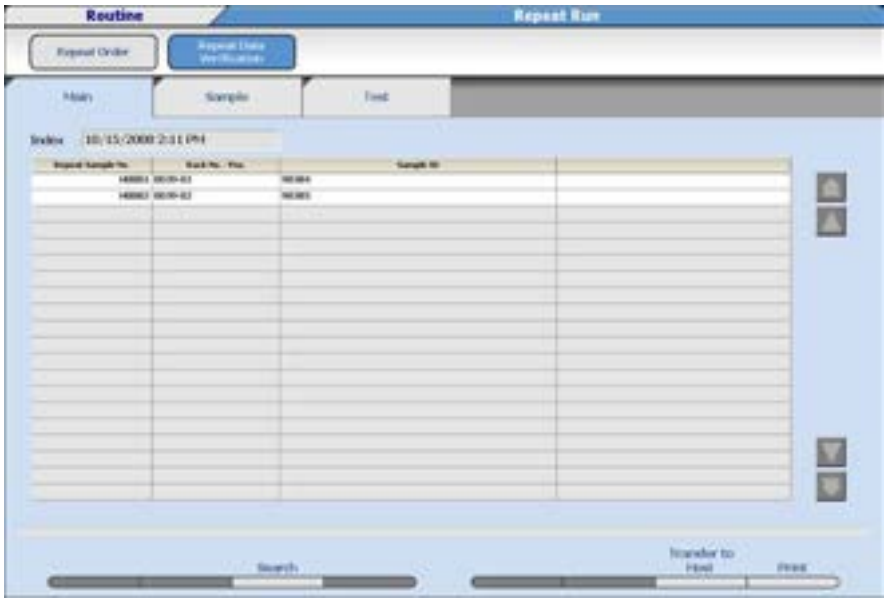
In **Reporter**, the system displays the Operator Name entered in the Start Condition screen. If necessary, enter a new name or use **Select** to enter a pre-programmed comment. Reporter is an option that can be added to a list format, and only prints if it is formatted.

4 Select **OK**.

Online Transfer of Overwritten Data

1 Select **Menu List > Routine > Repeat Run > Repeat Data Verification > Main**.

Figure 4.35 Repeat Data Verification: Main Tab



NOTE

The screen displays the current Index and data. Select **OK** if No Data Found displays.

2 Select **Search (F3)** to search for data by an Index, Sample Numbers, Sample ID, Data Not Transferred to Host, or Data Not Printed.

3 Select **Transfer to Host (F7)**. The Transfer to Online dialog opens.

4 Select **OK**. Online data transfer is performed.

To cancel the online data transfer, select **Online Transfer Stop (F7)**. Online data transfer is cancelled.

Edit Analysis Data

If the analysis data is manually edited, the edited data is displayed with an e flag indicating manual data edit. If the analysis data has been edited using a correction formula, the edited data is displayed with a c flag indicating manual data correction.

- Edit analysis data
- Edit analysis data using a correction formula
- Recalculation of analysis data using a previous calibration curve
- Transfer the edited data online

CAUTION

Editing should only be performed according to your laboratory procedures.

Edit Patient Sample Data

Results and flags can be reviewed and edited. If a result or flag is edited, an e flag is attached to the result.

1 Select **Home > Sample Manager > Sample > Main**. A list of samples in the index is displayed.

Figure 4.36 Sample: Main Tab

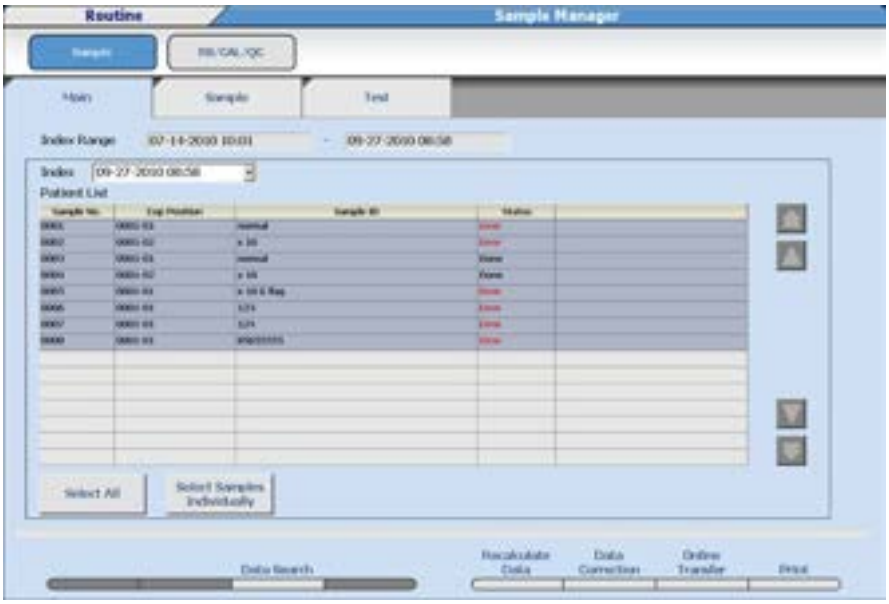


Table 4.8 Main Tab Description

Option	Description
Select All	All samples displayed in the list are selected (highlighted in gray).
Select Samples Individually	All samples displayed in the list are de-selected.
Recalculate Data (F5)	Re-calculate results using a previous calibration factor.
Data Correction (F6)	Correction by A and B of the correction coefficient AX + B is possible by test and by sample type.
Print (F8)	Print the selected samples in a list format.

2 Select **Data Search (F3)** to search for data by an Index Range, Sample Number, Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.

3 Select **OK** to update the contents of the Main tab.

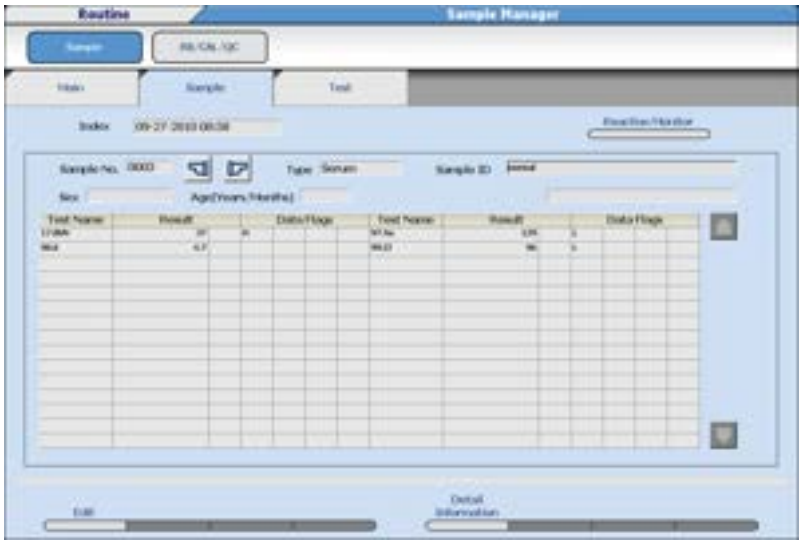
4 Select the **Sample No.** for the sample number to edit.

— Select **Select All** to select all samples displayed.
— Select **Select Samples Individually** to cancel the selection.

The selected samples are displayed in gray color.

5 Select the **Sample** tab or **Test** tab. The search results are displayed.

Figure 4.37 Sample: Sample Tab



Results and data flags can be reviewed and edited. If a result is edited, an e flag is attached to the result.

If the data indicates problems, select **Reaction Monitor** to display the Reaction Monitor screen and review specific information regarding the sample. Select **Back** in the Reaction Monitor screen to return to the Sample Manager screen.

6 Select **Edit (F1)**. Results or flags can be edited.

7 In the Sample tab, select the Test Name to perform edits. In the Test tab, select the Sample No. to perform edits. Select **Detail Information (F5)** to view the sample dilution rate, reagent lot number, and reagent bottle number.

8 Edit the desired result or data flags.

9 Select **Confirm (F1)** to save the edited data.

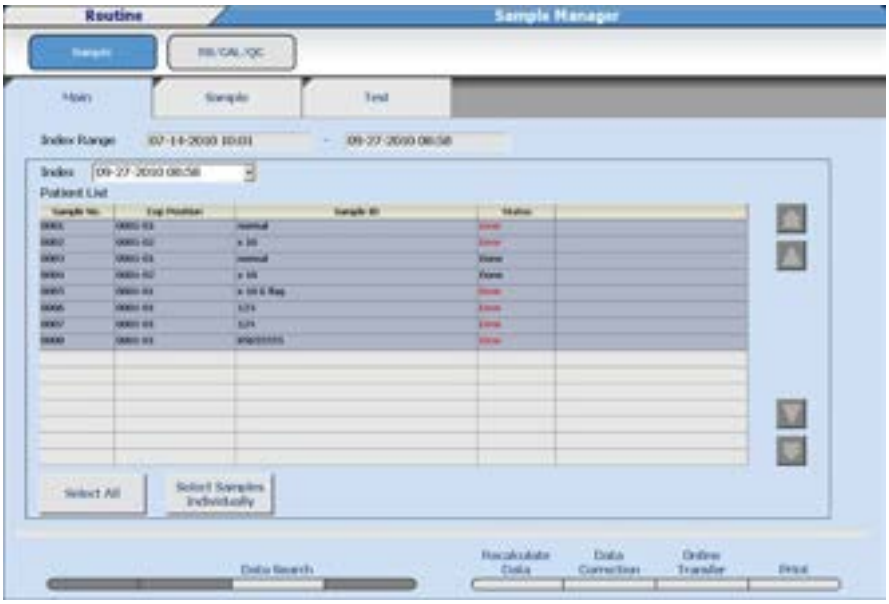
Correct Patient Sample Data

The correction formula Y = AX + B is used to correct the data for the selected samples by test or all tests.

- Y: Data after correction
- X: Data before correction
- A, B: An optional correction factor (9 digits, including sign and decimal point)

1 Select **Home > Sample Manager > Sample > Main**.

Figure 4.38 Sample: Main Tab



The screen displays the current index data.

2 Select **Data Search (F3)** to search for data by an Index Range, Sample Number(s), Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.

Figure 4.39 Data Search Dialog

3 Select **OK**. The Main tab displays with the samples found using the search criteria.

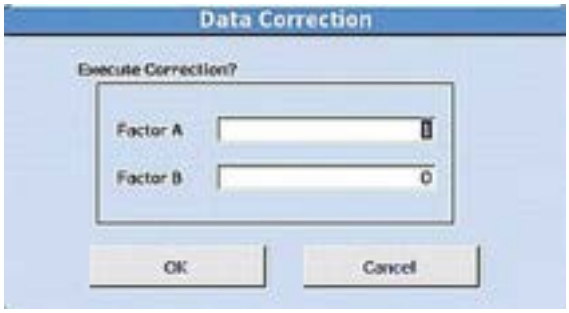
4 Select **Data Correction (F6)**. The Data Correction dialog opens.

Figure 4.40 Data Correction Dialog

5 Select the test to be corrected or select **All** from **Test Name** and then select **Correction**.

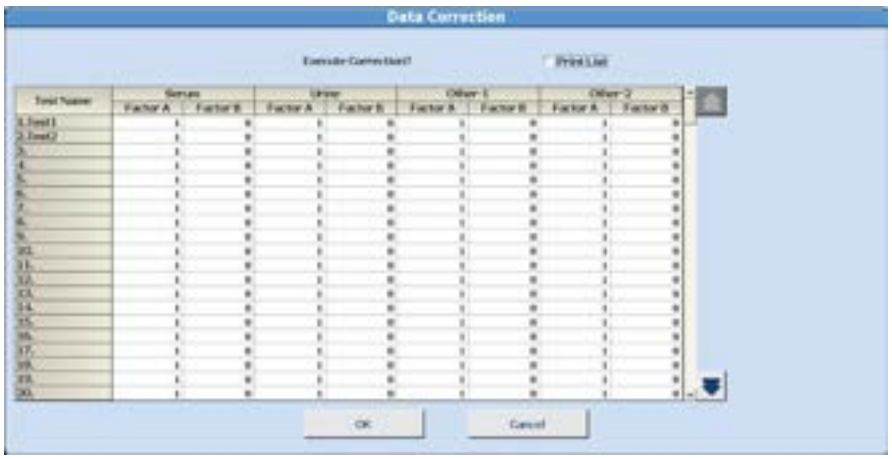
When a specific test has been selected, the dialog to enter factors A and B opens.

Figure 4.41 Data Correction Dialog (One Test Selected)



When **All** has been selected, the dialog for programming the factors A and B for all tests opens. Select **Print List** to print the factor list.

Figure 4.42 Data Correction Dialog (All Tests Selected)



6 Enter the factors A and B and select **OK**.

The Data Correction dialog opens with the message `Operating: Please wait`. When the correction is complete, a message appears with the last sample number corrected.

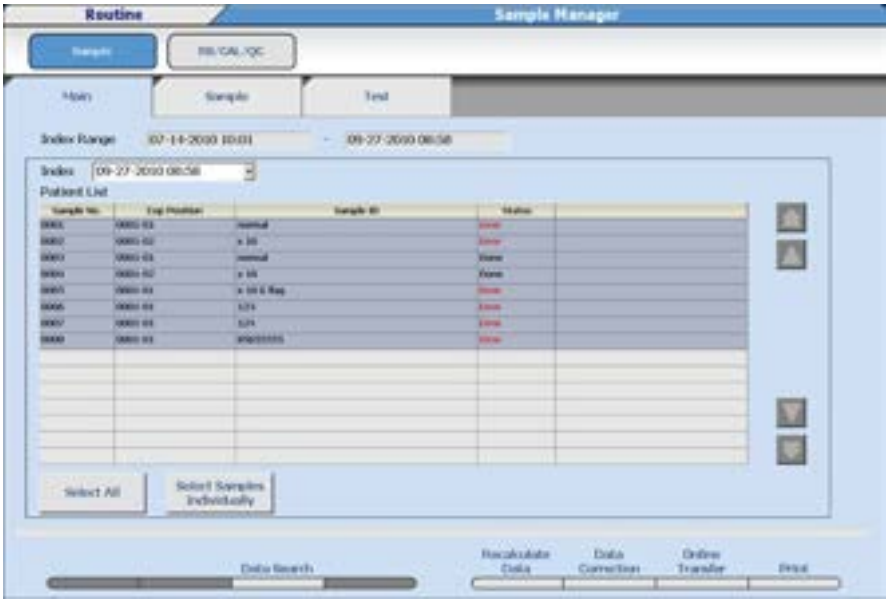
7 Select **OK**. The dialog closes and returns to the Main tab.

A c flag is attached to any result that has been corrected.

Recalculate Analysis Data Using a Previous Calibration Curve

1 Select **Home > Sample Manager > Sample > Main**.

Figure 4.43 Sample: Main Tab



2 The data from the current index displays. Select **Data Search (F3)** to search for data by an Index Range, Sample Number, Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data.

3 Select **Recalculate Data (F5)**. The Recalculate Data dialog opens.

Figure 4.44 Recalculate Data Dialog

4 Select the test to be recalculated from **Test Name**.

5 Select **OK**.

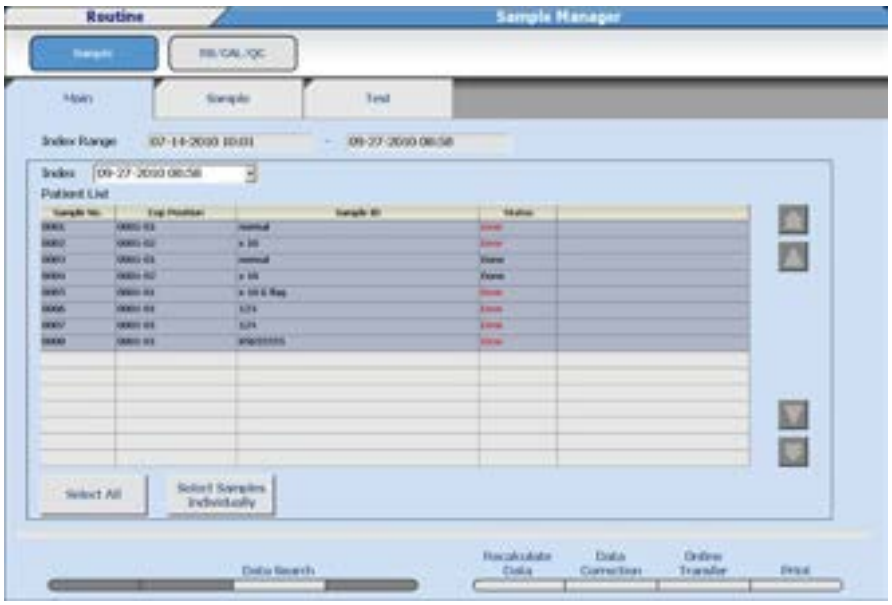
When the recalculation is complete, a message appears with the last sample number involved in the recalculation. A dialog displays `No Data Found` if the test was not included in the search criteria. There is not a flag attached to the recalculated data.

Transfer the Edited Data Online

Online transfer is possible if **Batch** or **Realtime** is selected for Result Transfer in **Menu List > System > Online**. For more information, refer to Online Menu.

1 Select **Home > Sample Manager > Sample > Main**.

Figure 4.45 Sample: Main Tab



2 The data from the current index displays with all samples selected (highlighted in gray). Select an index from **Index**.

Use **Select All**, **Select Samples Individually**, or select **Sample No. (s)** individually to transfer to the laboratory information system.

3 Select **Data Search (F3)** to search for data by an Index Range, Sample Number, Sample ID, Data Not Transferred to Host, Data Not Printed, or Abnormal Data. Select **OK**.

4 Select **Online Transfer (F7)**. The Online Transfer dialog opens.

5 Select **OK**. The data is transferred.

Select **Online Transfer Stop (F7)** to stop the transfer.

Calculate Data Statistics

The statistical values of analyzed patient sample results are displayed with graphs and numerical data, providing easy-to-understand views such as variations in test results and changes in the same sample.

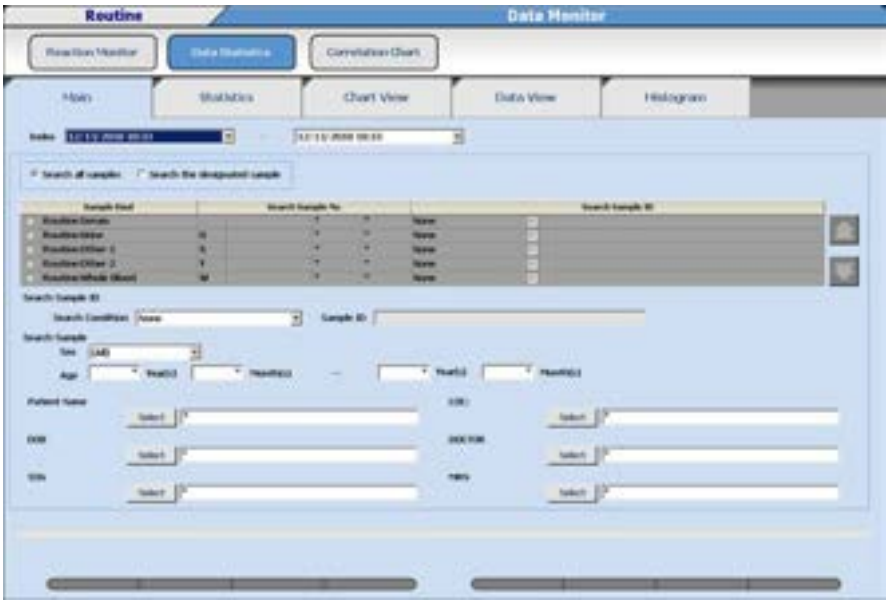
View Data Statistics

Review key statistics of sample results over a specified range of indexes.

To select samples to be used to generate sample statistics:

1 Select **Menu List > Routine > Data Monitor > Data Statistics > Main**.

Figure 4.46 Data Statistics: Main Tab



2 Select the index range from **Index**.

3 Select **Search all samples** or **Search the designated sample**.

4 If **Search all samples** is selected, a specific sample ID can be searched. Under Search Sample ID, select **Complete** or **Partial** to match the sample ID from **Search Condition**. Enter the sample ID to search in Sample ID.

5 When **Search the designated sample** is selected, set the search conditions from the list. Check the Sample Kind to search. The Search Sample No. and Search Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers. Enter a specific sample number or sample ID to search as required.

6 Set the search conditions (Sex, Age range, and/or patient demographic information 1 to 6).

User-defined patient demographic information is programmed in **System > Format > Requisition Format**.

7 Select the **Statistics** tab to display the data statistics, including the number of data points, mean, SD, CV (%), range, and maximum and minimum results.

Figure 4.47 Data Statistics: Statistics Tab

Select **Sorting List (F1)** to change the sorting order of the data display. Select **Test Name** to display tests in test number order from 1 to 120, **Num of Data** to display tests from the highest to lowest number of data points, and **CV(%)** to display tests from the highest to lowest CV. Select **OK**.

---

8 Select up to 12 tests to display data statistics in the Chart View, Data View, or Histogram tabs.

---

9 Select the **Chart View** tab to display data statistics and a graph.

Figure 4.48 Data Statistics: Chart View Tab

Select a test in **Test Name** to display the statistical information for that test in **Statistics**. The test selected displays with a thick line on the graph. Select a specific date, time, result, or sample number displayed on the X axis of the graph to display the information in **Detail Data**.

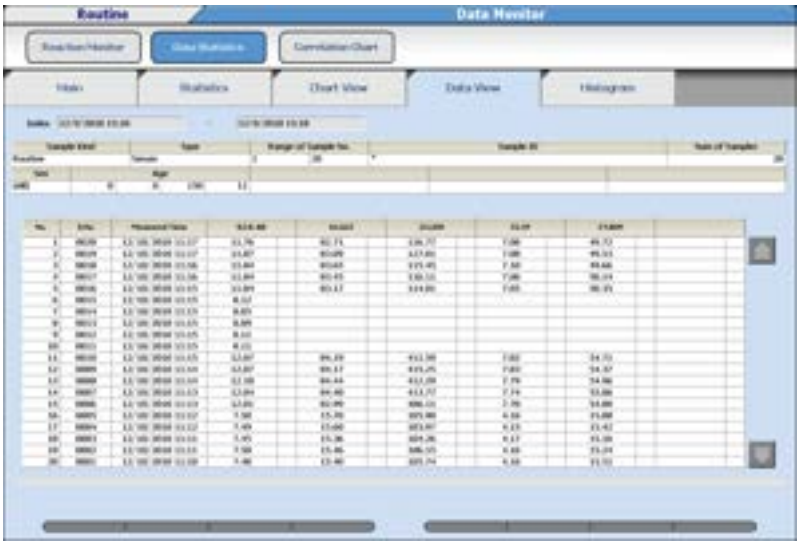
10 To change the graph display parameters, select **Graph Scale (F5)**. The Graph Scale dialog opens.

Figure 4.49 Graph Scale Dialog

11 Select the **Number of Display** and **X Scale** option required, then **OK**. The graph display changes.

12 Select the **Data View** tab to display the sample numbers, measure times, and results for the tests selected in the Statistics tab.

Figure 4.50 Data Statistics: Data View Tab



Data corresponding to 10,000 samples can be displayed using the up or down scroll button.

Change the test display using the left or right scroll button.

13 Select the **Histogram** tab to display test data statistics and a bar graph of the data.

Figure 4.51 Data Statistics: Histogram Tab

Data within the range of the mean +/- 1 SD is displayed by a blue bar. Data outside of the mean +/- 1 SD is displayed by an orange bar.

14 Select the test name from **Test Name**.

15 Select **Change Display Range (F5)** to change the display range of the histogram.

— Select **Auto Scale** to display the entire range of results.
— Enter the lowest result and highest result to display in **Range of Display**. Select **OK**.

Figure 4.52 Change Display Range Dialog

Create a Correlation Chart

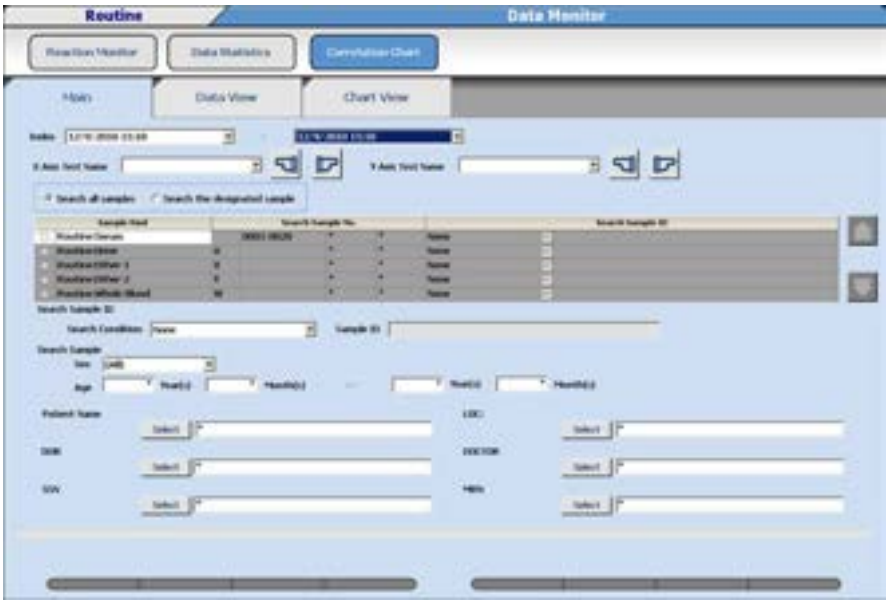
The Correlation Chart allows a comparison of two tests on the same samples within a specified index range.

This function calculates how well two tests correlate using different parameters.

To create a correlation chart, take the following steps.

1 Select **Menu List > Routine > Data Monitor > Correlation Chart > Main**.

Figure 4.53 Correlation Chart: Main Tab



2 Select the index range from **Index**.

3 Select the respective test name from **X Axis Test Name** and **Y Axis Test Name**.

4 Select **Search all samples** or **Search the designated sample**.

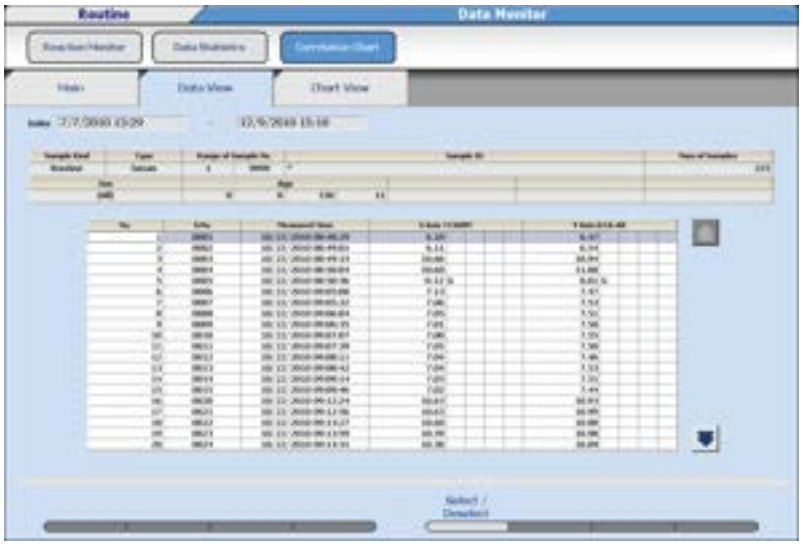
5 If **Search all samples** is selected, a specific sample ID can be searched. Under Search Sample ID, select **Complete** or **Partial** to match the sample ID from **Search Condition**. Enter the sample ID to search in Sample ID.

6 When **Search the designated sample** is selected, enter the search conditions. Check the **Sample Kind** to search. The Search Sample No. and Search Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers. Enter a specific sample number or sample ID to search as required.

7 Set the search conditions (Sex, Age range, and/or patient demographic information 1 to 6) as required.

8 To exclude data from the correlation chart, select the **Data View** tab.

Figure 4.54 Correlation Chart: Data View Tab



Data corresponding to 10,000 samples can be displayed using the up or down scroll button.

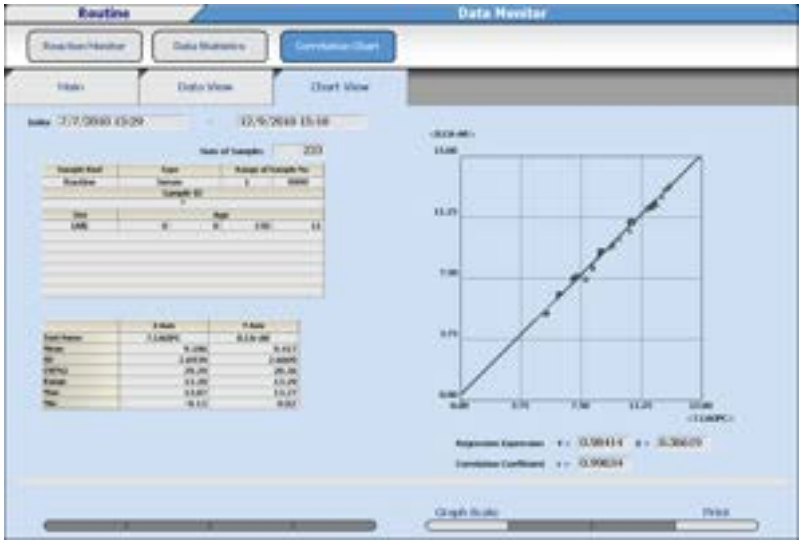
9 Select the item to be excluded.

10 Select **Select/Deselect (F5)**.

The color of the item row changes and the item is deleted from the Chart View tab. If **Select/Deselect (F5)** is selected again, the item is restored. The background color of the excluded sample becomes pink.

11 Select the **Chart View** tab to display the correlation chart.

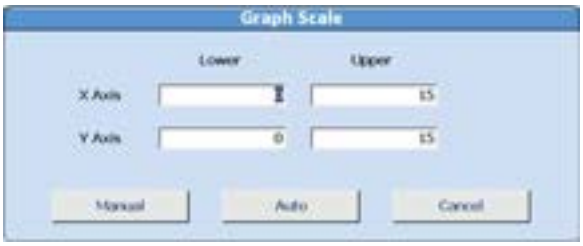
Figure 4.55 Correlation Chart: Chart View Tab



12 To change the display size of a correlation chart, select **Graph Scale (F5)**.

— When **Auto** is selected, the correlation chart displays the maximum range of all the data.
— Set the lower limits (Lower) and upper limits (Upper) for both the X Axis and Y Axis. Select **Manual** to display the correlation chart with the defined limits.

Figure 4.56 Graph Scale Dialog



13 To print the statistics and correlation chart, select **Print (F8)**. The Print Start dialog displays. Select **OK**.

Data Management

Data can be stored on external storage media to be used on a separate computer.

Parameters can be backed up on external storage media to be used to recover if the hard drive of the computer becomes inoperable.

WARNING

CD-ROMs and external USB storage devices such as flash drives and memory sticks increase the potential of harmful viruses infecting the analyzer's computer. To avoid damage to the computer and the data, before loading or saving data to any storage media, always perform a virus check on the media using any commercially available virus protection software, to ensure the media is free from harmful viruses.

Precautions for using external storage:

- Format the floppy disk for data or parameters. Set the write protect tab to the lock position after saving data.
- Inspect for viruses on a separate computer for floppy disks, CD-Rs, or USB flash drives and confirm that no viruses are detected before inserting the media into the analyzer computer.
- When using a CD-R, write data on the CD-R and set it to unrecordable.

NOTE

Virus pattern files are information files necessary for virus detection. Update antivirus software with the latest virus pattern files from the antivirus software manufacturer regularly. Contact the antivirus manufacturer if needed.

NOTE

U3 USB devices are not compatible with the analyzer software.

From the **External Data Management** menu, analysis results can be transferred to an external storage media by index.

For details on programming conditions to save or output the analysis results, refer to Offline Criteria in this chapter.

External Storage Device

Transfer data using the following external storage media.

- CD-R
- Floppy disk (FD)
- Optional external storage devices (HD) connected by USB.

CAUTION

- **The system only uses CD-R disks to transfer data using the CD drive. CD-RW and DVD disks are incompatible with the CD drive and cannot be used.**
- **Only 2HD FD can be used. 2DD FD cannot be used.**

Data that can be saved to external media:

- Patient samples (normal samples, emergency samples, STAT samples)
- Repeat Run samples
- Reagent blank, calibrator, and quality control samples
- Parameters

Save Data to External Media

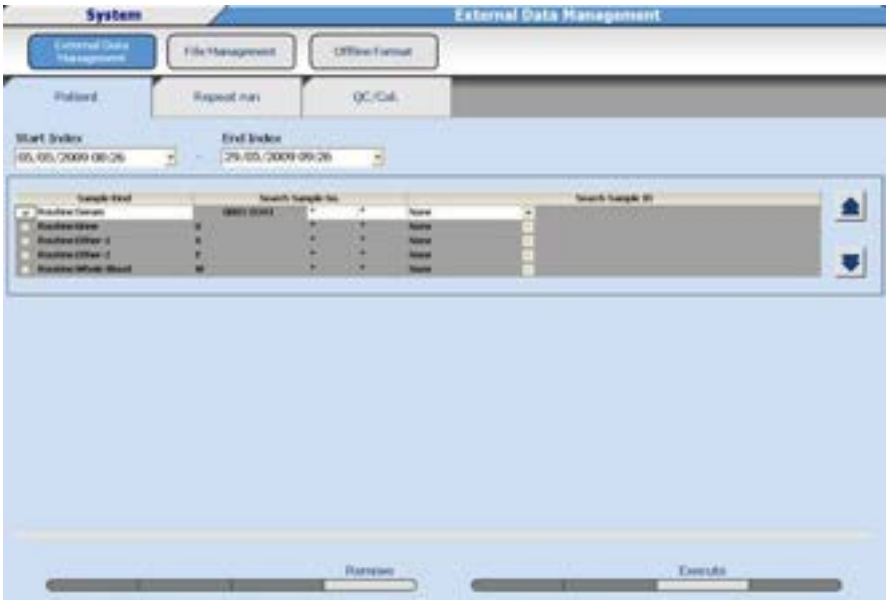
Save analysis data to external media for a backup of data, or to transfer the data to another computer. Data is saved to an AU Data folder. The data files are identified by the index. For example: `20100405_0732_000.csv` is data saved from the index April 5, 2010 at 07:32. If data is saved from the same index again, the file would be `20100405_0732_001.csv`.

Sample data, repeat sample data, reagent blank, calibration, and QC data can be saved to external media.

Save Samples (routine, emergency, and STAT), Repeat Samples, Reagent Blank, Calibration, and QC Data

1 Select **Menu List > System > External Data Management > External Data Management**.

Figure 4.57 External Data Management: Patient Tab



2 Select the **Patient** tab to save routine, emergency, and STAT samples, the **Repeat run** tab to save repeat samples, or the **QC/Cal.** tab to save reagent blank, calibration, or QC samples.

3 Select the start index and end index from **Start Index** and **End Index**.

4 Select the Sample Kind to save. Enter the Search Sample No. and Search Sample ID number to save, or leave the asterisk to save all data. Use the up or down buttons to change to Emergency or STAT samples.

5 Select **Execute (F7)**. Confirm the Total Output Samples and <Number of Output Sample> information.

Figure 4.58 Data Output Dialog

6 Select **FD**, **CD-R**, or **External Memory Unit**.

7 Select **OK**. The Data Output dialog opens and displays a confirmation message.

8 Select **OK**. A Data Output dialog displays a comment and the save progress.

A confirmation or warning message appears depending on the save progress.

A comment indicating the data save has been successfully completed appears on the Data Output dialog.

9 Select **OK**. Remove the media.

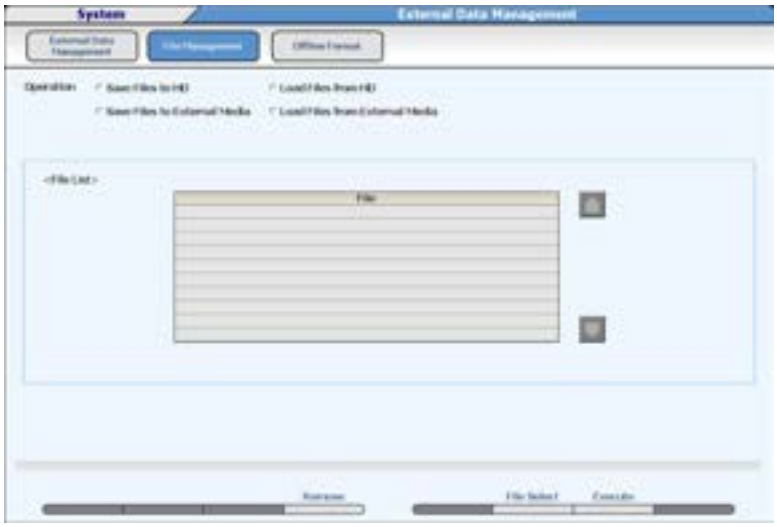
Save or Load Parameters

The system can save or load parameters to a backup folder on the hard drive or external media. Beckman Coulter recommends saving parameters when programming changes are made, or following your laboratory procedure.

If there are multiple AU680s in the laboratory, Beckman Coulter recommends saving the parameter files for each AU680 on separate external media.

1 Select **Menu List > System > External Data Management > File Management**.

Figure 4.59 External Data Management: File Management Screen



2 In **Operation**, select **Save Files to HD**, **Load Files from HD**, **Save Files to External Media**, or **Load Files from External Media**.

Saving or loading files to HD is a backup folder on the hard drive.

3 Select **File Select (F6)**. The File Select dialog opens.

Figure 4.60 File Select Dialog

4 Select the files to be saved or loaded. Select a menu from the left column to include all the submenus, or select only the submenu from the right column.

5 Select **OK**. The selected files are displayed.

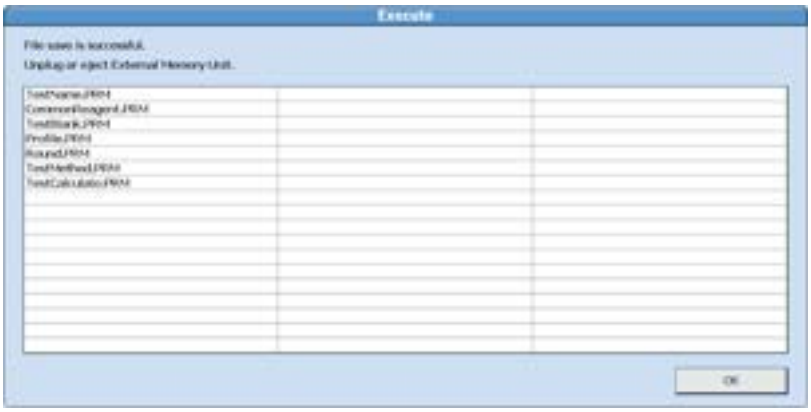
6 Select **Execute (F7)**. If saving or loading using external media, select **FD**, **CD-R**, or **External Memory Unit**, then **OK**. `Insert Disk. Start?` or `Connect External Memory Unit. Start?` displays. Select **OK**.

The Execute dialog displays when the operation is complete.

CAUTION

In the case of saving parameters to HD, FD, CD-R, or External Memory Unit, the existing parameters are overwritten without warning.

Figure 4.61 Execute Dialog



7 Select **OK**. The external media can be removed.

Offline Criteria

Program the criteria for saving analysis data (samples, repeats, reagent blank, calibration, and QC) and parameter files to external media.

Select **Menu List > System > External Data Management > Offline Format > Common Condition**.

Figure 4.62 Offline Format: Common Condition Tab

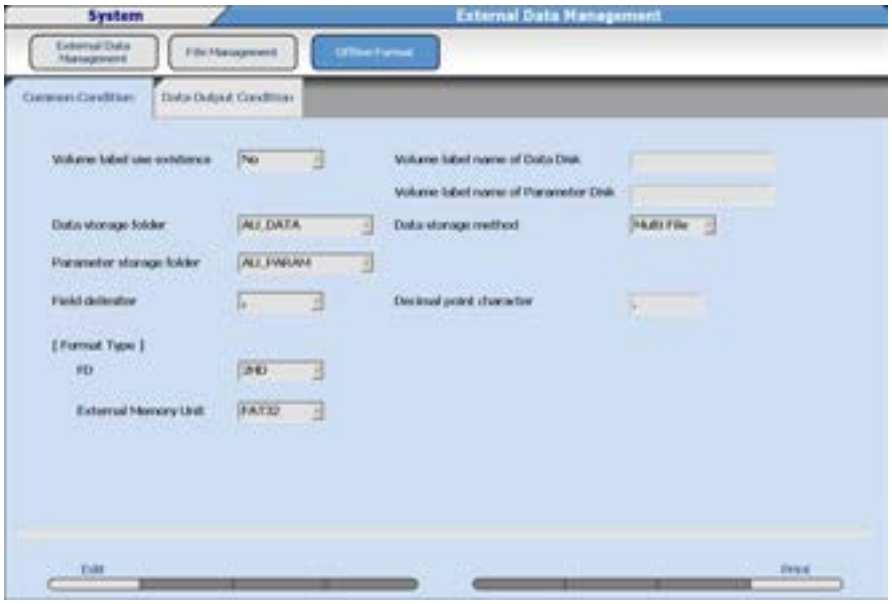


Table 4.9 Common Condition Tab Description

Option	Description
Volume Label Use Existence	— Yes: If the volume name registered on the medium does not match the entered name in Volume Label Name the medium is rejected. — No: The volume name is not checked.
Data Storage Folder	— AU_DATA: Folder AU_DATA is created, and data files are saved in it. — Root: A folder is not created. The data files are saved directly below the root.
Data Storage Method	— Multi File: The record numbers of files belonging to the same index are added, and saved as different files. — Single File: Files belonging to the same index are saved after over writing.
Parameter Storage Folder	— AU_PARAM: The folder AU_PARAM is created, and parameter files are saved in it. — Root: A folder is not created. The parameter files are saved directly below the root.

Table 4.9 Common Condition Tab Description (Continued)

Option	Description
Field Delimiter	Defines the delimiter to be added between each item of data.
Format Type	Specifies the format type for each medium. — FD:2HD — External Memory Unit : FAT32
Data filename	AU_YYYYMMDD_HHMM_XXX.csv — YYYYMMDD_HHMM: Year, month, day, hours, minutes of index — XXX: Record No. 000 - 999 — When the storage method is specified in one file, the Record No. is fixed at 000

Set Common Conditions

1 Select **Edit (F1)**.

2 Select **Yes** or **No** from **Volume label use existence** in order to set whether or not to use a volume name for the data output medium.

3 Select a data storage folder from **Data storage folder**.

4 Select the data storage method from **Data storage method**. Select multiple files or one file. When multiple files are selected, in the case where files belonging to the same index were saved, they are saved as different files without being overwritten.

5 Select the file storage folder from **Parameter storage folder**.

6 Select the field delimiter from **Field delimiter**.

7 Select **FAT32** from **External Memory Unit**.

8 Select **Confirm (F1)** to save the programmed values.

Data Output Conditions

1 Select **Menu List > System > External Data Management > Offline Format > Data Output Condition**.

Figure 4.63 Offline Format: Data Output Condition Tab

Table 4.10 Data Output Condition Tab Description

Option	Description
Field Number Limitation	Yes: A cautionary message is displayed if the number of fields (number of sets of item data) is set to 256 or more. If the number of fields is 256 or more, an Excel display cannot be made.
"DB" Record Use Existence	Yes: DB is added to the beginning of the record data string.
"DE" Record Use Existence	Yes: DE is added to the end of the record data string.
Information Block Use Existence	Yes: The field name and test name are added after DB at the beginning of the record data string.
Output Date Field Use Existence	Yes: The date and time data which outputs files is added after DE at the end of the record data string.
Output Condition of Sample Block	Sets the items to be output by the sample information.
Output Condition of Test Block	Sets the items to be output by the data for each item.
Item Order	Sets the test items to be output by the data.

2 Select **Edit (F1)**. The screen changes to edit mode.

3 Select **Yes** or **No** from **Field number limitation**, **DB Record Use Existence**, **DE Record Use Existence**, **Information Block Use Existence**, and **Output date Field Use Existence**.

4 Select the sample block output conditions to be output. Conditions displayed in gray can be confirmed but not changed.

5 Select **Item Order (F5)**. The Test Order dialog opens.

6 Select the item to be offline output.

7 Select **OK**.

8 Select **Confirm (F1)** to save the programmed values.

Using Beckman Coulter PROService (Option)

Beckman Coulter PROService allows operators to manually transmit the AU680's various parameters to the Beckman Coulter service center. The Beckman Coulter service center can check operating status and troubleshoot problems with this information.

Transmittable parameters and data on the PROService screen include the following:

- Files such as analysis parameters and system settings in the parameter menu.
- Analysis data.
- Files such as the operation and alarm logs.
- Other files about the program version, and so forth.

The PROService function does not transmit personal information such as patient information. PROService is an option requiring a separate support contract. For more information, contact Beckman Coulter.

Transmit Files with PROService

1 Select **Home > Analyzer Maintenance > PROService**.

Figure 4.64 User Maintenance: PROService Screen

NOTE

F5 displays **Connect** (not connected) or **Stop** (connected) to indicate the connection status of PROService. If PROService is not connected, select **Connect (F5)** to connect PROService.

2 Select the data to be transmitted.

3 Select **File Transfer (F8)**. A transmission start confirmation message appears.

4 Select **OK** to transmit the files. The transmission is complete when the message `Please wait` disappears.

APPENDIX A

Specifications

Sample Bar Code Specifications

Analysis can be executed by using a bar code label as a sample ID. The following sections define the bar code specifications used for identifying samples on the AU680.

Bar Code Type

Sample bar codes include the following types:

- NW-7
- CODE 39
- CODE 128, ISBT-CODE 128
- INT (Interleaved 2 of 5)
- Standard 2 of 5

The system can read multiple bar codes when using a mixture of NW-7, CODE 39, CODE 128, INT (interleaved 2 of 5), or Standard 2 of 5. The specifications of individual bar codes comply with the following standards.

Table A.1 Compatible Standard

Bar Code	Compatible Standard
NW-7	JIS-X-0506, USS-NW7
CODE 39	JIS-X-0503, USS-CODE 39
CODE 128	JIS-X-0504, USS-CODE 128
ISBT-CODE 128	ISBT 128
INT (Interleaved 2 of 5)	JIS-X-0502, USS-I2/5

Table A.2 Character Font

Bar Code	Character Font
NW-7	0 to 9
CODE 39	Alphanumerics, special characters
CODE 128	Alphanumerics, special characters
ISBT-CODE 128	Alphanumerics, special characters
INT (Interleaved 2 of 5)	0 to 9
Standard 2 of 5	0 to 9

Bar Code Digit Number

Maximum 26 digits

NOTE

Refer to the Laboratory Automation System manual for bar code types available when the AU680 is connected to a laboratory automation system.

The bar code digit specification is 0 to 17 digits when the AU680 is connected to a laboratory automation system.

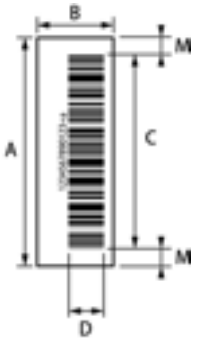
Label Size

The size of sample bar code labels must follow the following specifications. (The unit is in millimeters.)

- Label length (A) < Sample tube length -12
- Label width (B): At least D+10mm, and not so wide that the label interferes with the bar code label area.
- Bar code height (D) ≥ 10
- Top/bottom margin (M): shown below

  CODE 128: 10 times the X dimension or 2.54, whichever is larger, or more (quiet zone)
  Other than CODE 128: 3 or more
- Bar code area (C) = A - 2 x M

Figure A.1 Sample Bar Code Label Specifications



Bar and Space Widths

Bar and space widths must be as follows:

Table A.3 Bar and Space Widths

	NB (narrow bar)	NS (narrow space)	WB (wide bar)	WS (wide space)	G (gap)	X[1] (size)
Min	0.165 to 0.2 mm	NB to 1.25 NB	2.2 NB to 3.0 NB	2.2 NB to 3.0 NB	NB to 3.0 NB	0.191 or more
Max	0.2 to 0.5 mm		2.0 NB to 3.0 NB	2.0 NB to 3.0 NB	NB to 3.0 NB	

1. In case of CODE 128

Bar Code Check Character

A bar code can be selected from the following three methods:

1. The check method is used from the following table.
2. No check character is used.
3. No check is performed although a check character is included.

Table A.4 Check Character Method

Bar Code	Check Character Method
NW-7	Least significant digit, MODULUS-16
CODE 39	Least significant digit, MODULUS-43
CODE 128, ISBT-CODE 128	Least significant digit, MODULUS-103
INT (Interleaved 2 of 5) and Standard 2 of 5	Least significant digit, MODULUS-10

CODE 128 and ISBT-CODE 128 require a check character. These codes cannot be selected with the above methods 2 and 3.

Bar Code Label Print

Print bar code labels according to the following requirements to maintain readout accuracy.

- PCS value

  If NB (narrow bar) width is between 0.165 and 0.50 mm the PCS value must be 0.60 or more.

  If NB (narrow bar) width is between 0.130 and 0.156 mm the PCS value must be 0.85 or more.

Figure A.2

$$\text{PCS Value} = \frac{R_L - R_D}{R_L}$$

R_L : white bar and margin reflection rate
R_D : black bar reflection rate

- CODE 128: MRD must be 37.5% or more.
- A void on a white bar (damage or print loss on a bar), ink spot (ink stain) and thin spot must meet the following requirements:
  - A spot diameter is 0.05 mm or less.
  - The void is 25% or less in a circular area with a diameter of 0.1 mm.
  - There is no marked blurring.

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