Quality Control and Acceptability

Audience All personnel in the Pulmonary Function Clinics.

Purpose Any measuring instrument used in diagnosis must be checked routinely to assure its reliability.

Policy Two methods of quality control are used to evaluate analyzer performance. One method is built-in (automatic), and the other is an ampoule-based (manual) method. The ABL 90 FLEX PLUS analyzer performs periodic checks to provide further confidence that the analyzer is performing to specification.

Built In (Automatic) QC

The traditional quality control assessment of the ABL90 FLEX analyzer is done on three separate and dedicated QC solutions, using the traditional QC concept of monitoring systematic trends occurring on the analyzer. The advantages of built-in QC include the following:

- Dedicated QC solutions, independent of calibration solutions.
- Analyzer construction ensures a check of the entire liquid pathway from inlet to waste collection, because all liquids run through the same pathway.
- The QC solution composition is close to patient matrix with regard to concentration, partial pressure, etc.
- Accuracy and precision can be monitored over a period of time.
- Detecting shifts or trends over time by monitoring systematic performance (Levey-Jennings plots).
- Values can be used for statistical interpretation, e.g. Westgard violations, etc.
- QC values can be observed in a peer comparison program.

Schedule

These automatic quality control measurements are performed during each System Cycle which is every 8 hours.

Control Ranges

The assigned value and control range for each parameter and level are entered automatically into the analyzer each time a new solution pack is installed.

QC Records & Data Logs

The analyzer logs all events, quality control, patient data and calibrations. Therapist can bring up data on the analyzer to detect shifts, trends, messages, and determine if analyzer needs further assessment and troubleshooting. See policy 04-08 Analyzer & Data Logs for more information.

Acceptance Criteria

The analyzer automatically assesses all automatic QC results and flags any result that is outside the control range. See policy 04-01.

System Checks & Analysis Checks

Automatic test sequences done with each measurement and at other times to ensure all parts of analyzer operate within specifications. Analysis checks are performed with every patient sample and as a minimum every second hour if no samples are run, according to the prescheduled calibration and QC activities.

Corrective Action

The analyzer automatically takes action to correct a problem it finds. Any errors that cannot be automatically corrected are displayed on the analyzer screen. If action fails, a message is shown, and the analyzer goes into Operator Action Needed, Troubleshooting needed or Intervention Required mode.

Ampoule-based (Manual) QC

In the ABL90 FLEX PLUS analyzer it is recommended to use the Radiometer brand quality control material QUALICHECK5+ for optimal performance. These QC materials cover high, medium, and low range levels.

QC Solutions & Registration

Before any new Lot number of QC is ran through the analyzer, the lot number of the QC solution must be manually registered before use. Radiometer QC solution information can be entered by scanning the barcode provided in the package insert that applies to the ABL 90. This process applies to Radiometer and non-Radiometer QC solutions. When a QC solution is registered, data about the solution is saved on the analyzer. The data is necessary to evaluate QC results.

QC Storage

Radiometer control material (QUALICHECK5+) should be stored between 2°C and 25°C (35.6°F to 77.0°F), including up to a total of 15 days at 32°C (89.6°F). Deviation from this temperature can cause value changes resulting in out-of-range QC results for oxygen, carbon dioxide and pH. Solutions are light and heat sensitive. Solutions are packed in light sealed cartons and stored in their boxes, in a cabinet or drawer if possible. Boxes should not be opened until time of use. Ambient room temperatures are logged daily per policy, 04-08. Unacceptable temperatures exceeding manufacturers' 15-day limit determine disposal of all Manual QC exposed, and suspension of analyzer use until new QC is ordered and introduced to analyzer. New Manual QC must pass before patient samples can be analyzed.

QC Handling

Handling of QC samples are done in the same process as patient samples. All QC samples are run by therapist working in the laboratory. For quality results, therapist will follow manufacturer's guidelines for QC measurements:

- Check for no Calibrations due before running QC.
- Solutions have been stored at correct temperature.
- Follows QC packet insert using manufacturer's instructions.
- Enters temperature correction during QC measurement.

QC Acceptability

Acceptance Criteria

The analyzer automatically assesses all Internal and External QC results and flags any result that is outside the normal range. Problems on built-in and ampoule-based QC results are marked with one or more of the symbols shown in the table.

Symbol	Description
?	An error was found. A message attached to the result describes the error.
↑↓	The result is outside the control range, but inside the statistical range. Results inside the statistical range are included in statistics.
↑↓	The result is outside the statistical range. The result is not included in statistics.
↑↓	The result is outside the range of indication*. The result is not included in statistics.
.....	The result could not be calculated. When possible, an interpretation of the message is attached.
*	Operator-defined slope/offset corrections were used to calculate the result
W	The result violates a Westgard rule
R	The result violates a RiliBÄK rule

The table describes the indications of QC being out of range or an error. The analyzer will display a troubleshooting message for the operator to follow. Although the ABL 90 analyzer provides consistent review on QC results, the performing therapist will also review and document any unacceptability in the ABG log. If QC is unacceptable, therapist will begin corrective action, troubleshooting and cease patient use of the analyzer until issue is resolved and QC is in range.

QC Statistics Statistics reported include current installed QC lot-to-date and bias-to-date.

Statistical parameters for currently installed QC lot (lot-to-date)

N	Number of QC measurements for currently installed QC lot
Mean	Mean value for lot
2SD	Shows how much variation there is from the mean
CV	Coefficient of variation

Statistical parameters for bias-to-date (current QC lot together with previous QC lots on a 3-month historical perspective; bias value is defined as the difference between the assigned and measured QC value)

N	Total number of QC measurements for this QC level

Mean (bias)	The mean bias for this parameter calculated with all performed measurements on this level 2SD Shows how much variation there is from the mean
CV (bias)	Coefficient of variation for bias = SD for bias/mean (lot–to-date)

QC statistics for bias values are based on QC measurements up to 3 months prior.

QC Plots

QC plots are Levey-Jennings plots that show QC results done with registered QC solutions. The results are shown on a horizontal time axis. With the use of Levey-Jennings plot the analyzer displays directly comparable QC values before and after QC lot changes. The Y-axis on the Levey-Jennings plot reflects the QC control ranges, and as the width of the control ranges are constant from one QC lot to another, the numerical difference between the upper and lower control range re- 14 mains constant between lots. The offset (absolute numbers of the control ranges) changes from lot to lot due to different assigned values. A QC lot change and thus new control ranges are marked with a bold line and the new control ranges are directly displayed in absolute numbers on the Levey-Jennings plot.

Quality Management Review

The QC statistics and results of controls are reviewed for acceptability before reporting test results. The laboratory participates in the manufacturer's Quality Manager program that tracks all the analyzers data and provides reports on analyzer issues, peer comparisons and QC statistical data. This data is monitored on a regular basis and minimally, monthly reviewed by Technical Consultant and Medical Director. See policy 04-08 Analyzer & Data Logs for more information. All QC records are kept for ***two years.***

Per manufacturer, the ABL 90 analyzer IQCP (Individualized Quality Control Plan) is not required as it features on-board control systems that use 3 or more levels of dedicated, NIST traceable QC material that tests the entire patient sample pathway, including the sample inlet, thus fulfilling the CLIA regulations for external quality control (Federal Register 493.1256c, 493.1267b, c). The ABL90 FLEX blood gas analyzer utilizes the AQM system for quality management. The heart of the system is three dedicated levels of NIST traceable quality control solutions contained in sealed pouches. During the QC measurement process the QC materials are treated in the same manner as a patient sample, including the inlet probe, completely challenging the entire analytic process as would be done with a manual external QC solution.
The QC statistical evaluation report will be reviewed monthly by the Technical Consultant and Medical Director. These reports will be saved in the PFT Laboratory digital shared drive.

Corrective Actions

One of the elements in the automatic quality management system is that necessary checks are done automatically and continuously. If a check fails, the check is in most cases repeated by the analyzer and, if possible, the analyzer remedies the malfunction automatically. If these actions fail, the analyzer enters the User Intervention Required (UIR) mode and the analyzer proposes corrective actions. This means that if an intervention by the user is required, the UIR mode screen appears with instructions on what to do in this case. The analyzer is locked until the UIR has been performed. Reference policy 04-01 Radiometer ABL 90.

Calibration Verification

Calibration verification will be performed on the ABL90 analyzer as part of ongoing quality control. Verification for the ABL90 FLEX PLUS laboratory is performed every six months (April and October). The lab will use Analytical Measurement Range (AMR) materials from manufacturer (Radiometer) and follow all manufacturer guidelines in performing the calibration verification (Linearity). The material provided by Radiometer include a low, medium, and high range of the AMR that will determine the accepted criteria for each parameter tested in the laboratory. Upon any failure of verification, Lab will cease operations, troubleshoot, and contact manufacturer for guidance. Laboratory will maintain records for two years.

Troubleshooting Procedure

Troubleshooting is necessary when the analyzer goes into an Operator Action Needed, Troubleshooting needed or Intervention Required mode. It may also be necessary to troubleshoot messages in the Analyzer status screen. In the troubleshooting modes, Troubleshooting needed and Operator Action Needed modes, text and video instructions guide you through each troubleshooting procedure and show you what to do to get out of the troubleshooting mode. After each troubleshooting procedure, the analyzer makes checks to find out if the issue has been resolved. If not, a new troubleshooting procedure is shown on the screen. If the guided troubleshooting procedures do not resolve the issue, the analyzer will go into the Intervention Required. Therapist can refer the manufacturer's IFU or contact Radiometer Representative for further assistance.

The QC Quality Management system is used for reviewing analyzer QC data, and it is reviewed monthly by Technical Consultant and Medical Director.

This form documents the approval and history of the policies and procedures for the Pulmonary Function Laboratory. The Medical Director signs all policies verifying initial approval. Annually thereafter, the Director and/or designee may approve reviews and revisions.

Date	Approved by:	Signature
11/07	**V. Cardenas, MD** **Medical Director Pulmonary Laboratory**	
6/09	**V. Cardenas, MD** **No changes to the policy**	
7/10	**V. Cardenas, MD** **No changes to the policy**	
2/12	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **No changes to the policy**	
4/14	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **Changes to policy**	
6/16	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **Changes to policy**	
11/17	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **No changes to policy**	
8/19	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **No changes to policy**	
2/22	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **Changes to policy**	
8/22	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **Changes to policy**	
8/23	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **Changes to policy**	