

|                                    |                 |        |
|------------------------------------|-----------------|--------|
| University of Texas Medical Branch | Effective Date: | Nov 95 |
| Pulmonary Function Clinic          | Revised Date:   | Sep 23 |
| Policy 04-08 Analyzer & Data Logs  | Review Date:    | Sep 23 |

## ABL90 FLEX CO-OX Analyzer & Data Logs

|                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Audience</b>     | All personnel in the Pulmonary Function Clinics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Purpose</b>      | To define the procedure for documenting, storage, and retention of data related to the ABL90 FLEX CO-OX analyzer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Policy</b>       | <p><i>Definition:</i> Data logs are historical files containing all patient, calibration and quality control measurements as well as a listing of pertinent system events. All data obtained is automatically stored in the logs from which the data can be viewed on the analyzer or downloaded to an external storage device. By law and for good laboratory practice, data generated must be maintained in an efficient and accurate manner. The following procedure assures that the above mentioned is achieved.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Introduction</b> | <p>The laboratory maintains information for many functions. These include:</p> <ul style="list-style-type: none"> <li>• ABL 90 Data Logs including Quality Manager program.</li> <li>• ABG Log – daily documentation</li> <li>• Patient Charge Sheets and ABG print out</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Data Logs</b>    | <p>The combination of data obtained from the built-in QC, calibrations, checks, etc. provides a matrix of data points that directly reflects the measuring quality and stability of the system across the measured range. The analyzer evaluates the data continually. If a problem is detected, it is automatically corrected, or a corrective action is prompted. If more detailed information is requested, the data logs can be consulted for the history of performed actions and results. The analyzer is set up not to report patient results if a calibration, analysis check, system check or QC error is present.</p> <p>Historical results for calibration, analysis checks, system checks, and quality control can be found in individual Data Logs.</p> <ul style="list-style-type: none"> <li>• The calibration log stores the calibration results.</li> <li>• The activity log stores analysis checks, system checks, actions to correct failed checks, rinse, and other wet section activities.</li> <li>• The quality control log stores built-in as well as external QC results, including the evaluation tools.</li> </ul> <p>To provide continuity between lots, the ABL90 FLEX analyzer generates a Levey-Jennings plot and QC statistics to provide trend and shift information across multiple solution packs and sensor cassettes. With monthly evaluation on actual QC values and a 3-month perspective by performing bias statistics the analyzer ensures the proper handling of different lots and preserves the historical perspective.</p> <p>Accession numbers are not applicable for specimens. The ABL90 analyzer does assign a sample number; however, this is not used because the results are</p> |

|                                    |                 |        |
|------------------------------------|-----------------|--------|
| University of Texas Medical Branch | Effective Date: | Nov 95 |
| Pulmonary Function Clinic          | Revised Date:   | Sep 23 |
| Policy 04-08 Analyzer & Data Logs  | Review Date:    | Sep 23 |

manually entered into the reporting software and patient medical record program. These programs are not digitally linked.

#### *Data Storage capacity*

|                      |                                                    |
|----------------------|----------------------------------------------------|
| Patient profiles log | Maximum 2000 patient profiles.                     |
| Patient results log  | Maximum 2000 results                               |
| Activity log         | Maximum 5000 activities                            |
| Calibration log      | Maximum 1000 results                               |
| Quality control log  | Maximum 2000 results                               |
| Replacements log     | This log is part of the Activity log               |
| Archived data logs   | 500 results from each log & 2000 from Activity log |
| System messages      | This log is part of the Activity log               |

#### *Quality Manager Program (Radiometer)*

The Quality Manager program is intended to assist operators to manage their quality processes and accreditation workflows for analytical devices. The ABL90 FLEX analyzer is supported by Radiometer's Quality Manager portal. The analyzer has full extensive communication capabilities, including the standard ASTM, HL7 and POCT1-A protocols, ensuring compatibility with most hospital IT systems. Radiometer's peer comparison program Worldwide DATACHECK (WDC) offers a web-based peer group comparison program for the ABL90 FLEX analyzer quality control data. Data is uploaded automatically to the web portal for peer group comparison with other ABL90 FLEX analyzers.

Quality Manager provides the following:

- Devices – number of devices, status of each device
- Issue List – number of current and/ or historical issues
- QC - latest QC, number of QC results, QC results with errors and QC results with range violations from the analyzer per day for the last 30 days, number of QC measurements has changed during a period of time and shows if an increased number of QC range violations or errors have occurred.
- Peer comparison - peer comparison status of all analyzers

#### *QC Reports*

A standardized report is generated from the Dashboard called QC statistical evaluation overview. This report shows an overview of the monthly quality control statistical evaluations. The QC statistical evaluation report shows bias and imprecision for a parameter on a device. Other report utilized are QC statistics overview and linearity. Each of these reports report shows QC range evaluations and the linearity of a parameter for a selected period of time.

#### *Peer Comparison Reports*

This report shows how your analyzers performed with regard to mean bias value and CV% compared to the peer group.

|                                    |                 |        |
|------------------------------------|-----------------|--------|
| University of Texas Medical Branch | Effective Date: | Nov 95 |
| Pulmonary Function Clinic          | Revised Date:   | Sep 23 |
| Policy 04-08 Analyzer & Data Logs  | Review Date:    | Sep 23 |

### *Issues Reports*

An issue tells the operator when it is necessary to take action to make sure your device gives accurate results. Issues can be resolved by listing corrective actions that were performed.

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.

### **ABG Log**

Therapists will maintain a daily log documenting date, time, ambient temperature, minimum and maximum temperature, humidity, barometric pressure, problems, actions, and results. Therapist can also log the status of ABL 90, and any other activity performed beyond sampling as needed. Documentation will include the following requirements:

1. Completed in blue or black ink, with a ballpoint pen (no gel ink or pencil).
2. No scratch outs or write overs.
3. No use of arrows or ditto marks to complete blank spaces.
4. If an error or typo is written, the therapist must strikethrough the error with drawing *one single line* through the incorrect information so as not to reduce the ability to read the error.
5. Any therapist or Director can correct the error.
6. Any comments explaining missing information must be explained and document on the same page. Therapist may use the back of the sheet, but not another page if room is not available.

Laboratory Technical Consultant performs documentation review of ABG Log monthly to assess issues with analyzer.

The ABG Log will be kept and stored for a period of two years from the date of the last entry on the log.

Temperature is monitored with a non-certified thermometer and hygrometer for temperature and humidity. Unless the laboratory has an appropriate thermometric standard device of known accuracy (certified to meet NIST) standards, a new monitoring device is purchased annually to maintain accuracy and will be dated with expiration date.

|                                    |                 |        |
|------------------------------------|-----------------|--------|
| University of Texas Medical Branch | Effective Date: | Nov 95 |
| Pulmonary Function Clinic          | Revised Date:   | Sep 23 |
| Policy 04-08 Analyzer & Data Logs  | Review Date:    | Sep 23 |

---

## Record Retention

The Laboratory will maintain records for a period of two years\*. The records are available and accessible for reference, if necessary. Records maintained includes the following:

1. ABG slips (Specimen printout), attached to charge sheet
2. Quality Management records – QC and QA
3. Method Comparison Study\* – kept for life of analyzer
4. Calibration verifications
5. Instrument maintenance – Service maintenance, recalls, software updates.
6. Competency / Training / CEUs
7. PFT Meeting minutes - QM/QI reviews
8. LOGS

The laboratory maintains service maintenance binder to track analyzer service, software updates and manufacturer recalls. These records are reviewed biennially with policies and procedures, and as needed.

**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.**

| <b>Date</b> | <b>Approved by:</b>                                                                | <b>Signature</b> |
|-------------|------------------------------------------------------------------------------------|------------------|
| 11/07       | V. Cardenas, MD<br>Medical Director Pulmonary Laboratory                           |                  |
| 6/09        | V. Cardenas, MD<br>No changes to the policy                                        |                  |
| 7/10        | V. Cardenas, MD<br>No changes to the policy                                        |                  |
| 2/12        | A. Duarte, MD<br>Medical Director Pulmonary Laboratory<br>No changes to the policy |                  |
| 4/14        | A. Duarte, MD<br>Medical Director Pulmonary Laboratory<br>Changes made to policy   |                  |
| 6/16        | A. Duarte, MD<br>Medical Director Pulmonary Laboratory<br>Changes made to policy   |                  |

|                                    |                 |        |
|------------------------------------|-----------------|--------|
| University of Texas Medical Branch | Effective Date: | Nov 95 |
| Pulmonary Function Clinic          | Revised Date:   | Sep 23 |
| Policy 04-08 Analyzer & Data Logs  | Review Date:    | Sep 23 |

**11/17**      **A. Duarte, MD**  
**Medical Director Pulmonary Laboratory**  
**Changes made to policy**

**8/19**      **A. Duarte, MD**  
**Medical Director Pulmonary Laboratory**  
**Changes made to policy**

**3/21**      **A. Duarte, MD**  
**Medical Director Pulmonary Laboratory**  
**Changes made 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**

**9/23**      **A. Duarte, MD**  
**Medical Director Pulmonary Laboratory**  
**Changes to policy**