Arterial Blood Gas Analyzer – Radiometer ABL 90 FLEX PLUS

Audience All personnel in the Pulmonary Function Clinics.

Policy The purpose of this policy is to define the usage of the Radiometer ABL90 FLEX PLUS for the analysis of arterial blood gas samples. The policy includes information regarding the operations, quality control, calibration, limitations and expected performance of the analyzer based on manufacturer's guidelines.

Analyzer Manufacturer & Principle

The Pulmonary Laboratory uses the ABL 90 FLEX PLUS analyzer and is manufactured by Radiometer America. This analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures pH, blood gases and oximetry in heparinized, arterial whole blood. The analyzer uses consumables (Solution Pack and Sensor Cassette) to obtain measured parameters that include pH, pCO2, pO2, tHb, sO2, O2Hb, COHb, and MetHb. The laboratory reports on these parameters and are performed under physician's orders. The analyzer is intended for use by trained respiratory therapist in a laboratory environment near point-of-care setting. The manufacturer recommendation is hands-on training in the functions relevant for the field of work.

Operation The ABL 90 remains in operation during the Pulmonary Function clinic hours of Monday 8:00 am to Friday 5:00 pm, when staff are in the laboratory. The analyzer performs routine system checks as needed during non-business hours and remains in operation during this time. Shutdown of the analyzer is performed only when troubleshooting and requested by manufacturer or during other emergencies. Start up time is up to 2 hours and is the period from when the Sensor Cassette was installed, and 3 levels of automatic QC are done. It includes the conditioning of the Sensor Cassette, calibration, and QC cycles.

Pre-Use Studies Upon initial use of the analyzer, a Method Comparison and Precision Study is performed. For the Precision study, the laboratory will use a minimum of 15 samples, and for the Method Comparison study, a minimum of thirty-five samples will be used. The Laboratory will may perform multi-site comparisons to ensure accuracy. The therapist will analyze samples and report per manufacturer guidelines. Studies will be analyzed by manufacturer for accuracy and precision. All study reports will be reviewed by Medical Director and Laboratory Supervisor before analyzer is approved for patient reporting. Method Comparison and Precision Study Reports will be kept with print outs for the duration of analyzer operation while in the laboratory.

Analyzer Specifications

Specification	Value
Start Up Time	W/O metabolite sensors: Up to 2 hours. Startup is timeframe from Sensor Cassette installed and 3 levels

	of automatic QC are done, and includes conditioning of Sensor Cassette, calibration, and QC cycles.
Volume of sample for aspiration	65 µL
Measuring time	35 seconds from time sample is aspirated until results are shown.
Measurement cycle time	60 sec from time sample is aspirated until analyzer is ready to analyze next sample. Time may be different during Start Up.
Printer	Built-in thermal printer
Operating Ambient Temp.	15 °C to 32 °C
Max altitude	3000m
Relative humidity	20-80%
Barometric Pressure	525-800mmHg (at ambient temperature)
Storage Temperature	-20 °C to 60 °C

Principles of Operation

Sensors

The operations manual refers to the term sensor an individual sensor as part of the sensing array within a Sensor Cassette. The electrical signal from each sensor is measured by proprietary analog electronics contained within the analyzer unit. The sensors are located on sensor boards in the Sensor Cassette.

Measurement Principles

There are four different measuring principles employed in sensors in the ABL 90 FLEX PLUS analyzer.

• **Potentiometry:** The potential of an electrode chain is measured by a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH, *p*CO2, K+, Na+, Ca2+, and Cl sensors.

• **Amperometry:** The magnitude of an electrical current that flows through an electrode chain is proportional to the concentration of the substance that is oxidized or reduced at a electrode in the chain. The amperometric measuring principle is applied in the *c*Glu and *c*Lac sensors.

• **Optical *p*O2:** The optical system for *p*O2 is based on the ability of O2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample. This measuring principle is applied in the *p*O2 sensor.

• **Spectrophotometry:** Light passes through a cuvette that contains a hemolyzed blood sample. The absorption spectrum is used to calculate oximetry parameters. This measuring principle is used for *c*tHb, *s*O2, *F*O2Hb, *F*COHb, *F*HHb, *F*MetHb and *F*HbF and *c*tBil*.

In potentiometry the potential of an electrode chain is related to the activity of a substance not its concentration. The activity of a substance can be considered the effective concentration of a species that takes non-ideality of the medium into account. The analyzer automatically converts activities into concentrations. The term

concentration is therefore used in explanations of the measuring principles for each of the sensors.

Reference Electrode

The purpose of the reference electrode is to provide a stable, fixed potential, against which the potential differences can be measured. The potential of the reference electrode is not changed by the sample composition. The reference electrode is used in the measurement of pH and electrolyte concentrations. Contact with the sample is made via a membrane junction between the reference electrode liquid chamber and the measuring chamber.

pH sensor

Potentiometric measurement principle

The pH and electrolyte sensors are measured according to the potentiometric measurement principle, where the potential of an electrode chain recorded at a voltmeter is related to the concentration of a substance via the Nernst equation. The Nernst equation lets you calculate the activity of known concentrations of samples (pH and electrolytes). The measured activities are used to calculate the concentrations using the calibration results of the analyzer.

Calibration of pH sensor

The sensitivity calibration of the pH and electrolyte sensors gives the slopes of the calibration lines. Status calibrations are done with every measurement to compensate for small variations in sensor performance between calibrations.

pCO2 sensor

The electrode chain measures the pCO2. The potential differences at all the junctions in the electrode chain are known and constant, except that at the pH-sensitive membrane. The potential difference at the pH-sensitive membrane depends on the pH of the electrolyte solution, which in turn depends on the CO2 content of the sample.

Measurement Process in the pCO2 sensor

Part	**Function**
Transport of CO2	CO2 from the sample permeates the membrane
Dissolution ofCO2	The CO2 dissolves in the electrolyte solution. This produces carbonic acid: $H_2O + CO_2 \Leftrightarrow H_2CO_3$
Dissociation of carbonic acid	Carbonic acid dissociates according to this equilibrium reaction: $H_2CO_3 \Leftrightarrow H^+ + HCO_3^-$
pH change	The release of H+ ions changes the H+ concentration, and thus the pH of the inner buffer solution on one side of the pH-sensitive membrane
Measurement of potential	The concentration gradient of H+ ions across the membrane creates a potential difference across the membrane. This change in potential across the membrane is measured by the voltmeter.
Relation of pH to	The structure of the pCO2 sensor is similar to the pH sensor,

pCO2 including the presence of a pH-sensitive membrane. The major difference is in the internal electrolyte solution present in the pCO2 sensor which allows the dissolution of CO2 and ultimate dissociation of carbonic acid mentioned above. If [cHCO3 -] and α in the electrolyte solution are constant, it results in this equation: pH = K - log pCO2 Where K contains the equilibrium constant pKa , the solubility coefficient α and the concentration of bicarbonate [cHCO3 -].

Calibration of the pCO2 sensor

The sensitivity calibration of the *p*CO2 sensor gives the slope of the calibration line. Status calibrations are done with every measurement to compensate for small variations in sensor performance between calibrations.

Calibration levels, Sensitivity, and Stability

The ABL90 FLEX PLUS analyzer is equipped with a Solution Pack. This pack contains precision-tonometered fluids. The tonometry calibration gas mixture is of a known composition. The partial pressure of CO2 (*p*CO2) and the solution pH values are known and contained in the Solution Pack smart chip. The sensitivity value shown in calibration results shows how much the sensitivity of a sensor differs from the sensitivity of a theoretical sensor. The sensor response stability is the standard deviation of the last 5 calculated status calibration values.

pO2 sensor

Optical system for pO2

The optical system for *p*O2 is based on the ability of O2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample.

Measurement sequence

The green LED emits light, which is reflected by a dichroic mirror onto the *p*O2 sensor. Due to the phosphorescence, red light is emitted back through the dichroic mirror and onto a photo detector. The photo detector sends the electrical signals, proportional to the light intensity, to the analog/digital converter and the data processing unit that calculates the *p*O2 concentration.

Calibration of the pO2 sensor

Ambient air is used to do a sensitivity calibration of the *p*O2 sensor. A status calibration is done before every measurement to check the performance of the sensor between sensitivity calibrations.

Sensitivity and Status

The sensitivity is defined as the percentage of the measured *p*O2 on ambient air compared to the reference value. In connection with the sensitivity calibration done on ambient air, also the CAL 1 solution is measured to obtain a status. This status aims to check performed calibration by comparing measured value of CAL 1 solution to reference value of CAL 1, given by the smart chip.

Calculation of pO2 values

On blood, *p*O2 is adjusted with the sensitivity value and the measured *p*O2. The measured value is applied as a second-order blood correction, to compensate for

the varying buffer value of blood, as a function of *p*O2 tension. Air bubbles in samples may collect in front of the *p*O2 sensor and cause incorrect results. However, the analyzer will detect them and attach a message to the results.

The optical system is based on a 256-wavelength spectrophotometer with a measuring range of 478-672nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.

Calibration materials

The optical system is calibrated at two points using these solutions:

• The S7770 *c*tHb Calibration Solution with a known dye concentration to determine the cuvette path length, *l*.

• A transparent solution from Solution Pack in the analyzer to determine the zero point, *Io*.

Solution Pack & Sensor Cassette

Please reference policy 04-11for information regarding the ABL 90 FLEX PLUS solution pack and sensor cassette functions, specifications, and compositions.

Quality Control (QC)

Quality control management is important as it evaluates the performance of the analyzer to ensure patient results are accurate and precise. The analyzer manages quality control automatically, and additional QC procedures can be done. Two forms of quality control are performed on the analyzer and defined by the manufacturer as: Built-in QC and Ampoule-based QC.

Built-in Quality Control (Automatic or Internal QC)

QC procedure	**Description**
System checks	-Automatic test sequences done with each measurement and at other times to ensure all parts of analyzer operate within specifications.
Built-in QC	-These are liquid QC measurements that are automatically done by the analyzer. The 3 QC solutions in the Solution Pack are used for these measurements.
Apply statistical rules to QC results.	-Helps operators to find errors, shifts, and trends. Symbols on results show when rules are violated.
Apply corrective action for QC errors	-Default corrective action for QC errors: • Color of the traffic light adjacent to the Quality control button in the Analyzer status screen changes to yellow • Parameter tab changes to yellow • The ? symbol will be shown on the parameter in patient results
Repress a parameter if there are any problems	-Done for proficiency testing only on an as needed basis only.

Patient samples cannot be analyzed while the analyzer is locked**.**

System Checks
The analyzer automatically takes action to correct a problem it finds. If action fails, a message is shown, and the analyzer goes into Operator Action Needed, Troubleshooting needed or Intervention Required mode. In these modes, operators are given instructions about what to do. Results of failed system checks are recorded in the Activity log. (See manufacturer's IFU for schedule). A status calibration of all parameters (except the oximetry parameters) is done before every patient, QC, and sensitivity calibration measurement.
QC Measurements
The QC solutions are automatically registered when the Solution Pack is installed. A chip on the Solution Pack supplies data about the solutions. The analyzer uses three levels of QC solution contained in the Solution Pack to do built-in QC measurements. These QC solutions are automatically registered in slots A, B and C when a Solution Pack is installed. **Note:** The solution in slot A is S9030, the solution in slot B is S9040 and the solution in slot C is S9050.
Built-in QC measurement frequency
A built-in QC measurement is scheduled to be done every 8 hours. One measurement a day is done with each QC solution. Built-in QC measurements are also scheduled by default to be done in connection with these activities:
• Replacement of the Solution Pack
• Replacement of the Sensor Cassette
• Startup

Ampoule-based Quality Control (External or Manual QC)

QC procedure	**Description**
Ampoule-based QC Measurements	-Manual QC measurements done with QC ampoules
Ampoule-based QC Measurements after Solution Pack and/or Sensor Cassette replacements	-The analyzer is locked until requested ampoule-based QC measurements are done.
Calibration verification Measurements	-Measurements that let you verify the calibration and reportable range of measured parameters

* Radiometer does not guarantee accurate, valid QC results, if non-Radiometer QC Solutions are used.

QC Solutions & Registration
Each lot of each level of QC solution must be manually registered before use. This 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. The ABL90 FLEX barcode on the product insert for each level of Radiometer QC solution supplies data about it.
Acceptance Criteria

The analyzer automatically assesses all Internal and External QC results and flags any result that is outside the normal range.

Calibration verification

Calibration verification is a process that lets you verify the calibration and reportable range of the parameters measured by the analyzer.
Calibration verification is a 3-stage process:

- **Stage 1:** Analyze as patient samples a minimum of three different levels of QC solution. Note: Analyzer refers to these measurements as calibration verification.
- **Stage 2:** Use the calibration-verification measurement results to verify the calibration and reportable range of the measured parameters.
- **Stage 3:** If necessary, change the reportable range of parameters.

Results for pH, *p*CO2 and *p*O2 must be corrected if temperature of ampoule during the measurement was above or below 25 °C.

Frequency of calibration verification

Calibration verification is performed **biannually** in the Pulmonary laboratory, and results are kept in the CAP binder for a two-year timeframe. Results are stored digitally in shared drive.

Calibration Criteria/Acceptability

Calibration verification (linearity) verifies the analytical measurement range (AMR) and is performed from the manufacturer's (Radiometer) kit. Information from each kit has a limits of acceptability sheet included that verifies acceptability of each parameter. Analyzer results are entered in the cells per manufacturer's guidelines and information is automatically calculated and plotted. The therapist performing linearity will enter information, print results, and save PFT Lab shared drive. Printed information is kept CAP binder for the current year.

Failed Calibration Verification (Linearity)

For any failed parameter on the linearity, the therapist will contact the manufacturer for assistance and the analyzer will not be utilized for patient results until calibration verification passes. The Technical Supervisor will be notified of any failed linearity testing and/or postponement.

QC Statistics

QC plot

The QC plot displays result of all automatic quality control measurements for each parameter and each solution level. QC plots are Levey-Jennings plots that show QC results done with registered QC solutions. The results are show on a horizontal time axis.

QC Results

Any errors on QC will show on the analyzer a question mark until the QC error is removed. The analyzer has defaulted to not allow patient samples to be analyzed until QC measurements are successfully completed. Troubleshooting procedures are listed in the manufacturer's IFU (available in PFT Lab shared electronic files and hard copy in the ABG office).

QC Records

All built-in and ampoule-based quality control results are stored in the analyzer's database.

QC Corrective Action

The analyzer is defaulted to notify operator of errors by changing color of traffic light on the operation screen to yellow or red. The analyzer will provide a message if an error is found. The message attached to results describes the error and will give an option for troubleshooting. Operator will follow instructions on screen and IFU as reference for troubleshooting. In the troubleshooting modes text and video instructions guide operator through each troubleshooting procedure and demonstrates what to do to get out of troubleshooting mode. After each troubleshooting procedure, the analyzer makes checks to find out if 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. At this point, the operator will contact the Radiometer Help Desk at 800-333-4137 or local Representative for assistance.

Calibration

Definition

Calibration is the process that relates the sensor signals during the calibration sequence to the values of the calibrating solutions and air. Calibration enables the sensor signals to be converted to the accurate values for an unknown sample. Calibration makes sure that measurement results are accurate and reliable. The analyzer calibrates most parameters automatically. Only the recommended sensitivity calibration of the oximetry parameters is manual. The calibration adjusts the optical system of the analyzer to make sure that the results of the oximetry parameters are accurate and reliable. The calibration materials in the solution pack are used for this calibration as well as for the automatic calibrations.

Calibration type	**Calibration identifiers**	
Automatic calibrations	**BG**	*p*O2
	BG, Met	*p*CO2
	pH	pH
	Oxi	Oximetry parameters
Manual calibration	**tHb** (recommended)	Sensitivity calibration of the oximetry parameters

Frequency

Automatic calibrations are scheduled by default to be done at regular intervals. This is necessary to compensate for small changes in the behavior of the sensors in the Sensor Cassette. This can also be done in connection with maintenance, replacements, troubleshooting and startup.

The following is a list of the Calibration Frequency:

Identifier	**Calibration**	**Material**	**Frequency**	**Start Time**
pH (pH)	Sensitivity	CAL 1 solution CAL 2 solution	Once a day	08:00 hours
	Status	CAL 1 solution	Every measurement	N/A
BG, Met (pCO2)	Sensitivity	CAL 1 solution CAL 3 solution	Every 4 hours	02:00 hours

	Status	CAL 1 solution	Every measurement	N/A
BG (pO2)	Sensitivity	CAL 1 solution Ambient air	Once a day	16:00 hours
	Status	CAL 1 solution	Every measurement	N/A
Oxi (oximetry Parameters)	Sensitivity	CAL 1 solution ctHb calibration solution (S7770)	Every 3 mos.	N/A
	Status	CAL 3 solution	• Every 4 hours • When temperature drift in the oximetry optical system is outside specified limits	N/A

Calibration solutions

CAL 1, CAL 2, and CAL 3 solutions are used for the calibration of sensors. Air is used for the calibration of the *p*O2 sensor. The calibration solutions contain known concentrations of the parameters to be measured. These concentrations are necessary to determine the measurement results. The concentrations are automatically read from a chip on the Solution Pack when the Solution Pack is installed.

Sensitivity

The sensitivity value shown in calibration results shows how much the sensitivity of a sensor differs from the sensitivity of a theoretical sensor. The sensitivity of a theoretical sensor is 100 %. If a sensor sensitivity is reported to be 95 %, its sensitivity is 5 % less than the theoretical sensor sensitivity. The sensitivity of a sensor is the slope of its calibration line. Each sensor has its own sensitivity limits. The sensitivities are range-checked:

	pH	pCO2	pO2
Min	85%	60%	85%
Max	105%	105%	110%

The calibration line slope is re-established with every calibration.

Status

The calibration status values are, in general, defined as the sensor signals of CAL 1 except for *p*O2, which is only calibrated in one point (*p*O2 status reflects the cal check).

Drift

Drift describes the variation in location of the calibration line between consecutive calibrations. A Status calibration is done with every measurement. This lets the analyzer automatically compensate for status drifts. Sensitivity drift is usually insignificant in comparison with status drift.

Parameters Some parameters are measured by the analyzer, others are calculated from equations that use measured / keyed-in / default values of other parameters.

Parameter type	Description
Measured(M)	Parameters that are measured by the analyzer
Input	Parameters that are keyed-in (entered) by an operator
Derived (D)	Parameters that are calculated from measured, input and default values (Acid/Base (AB) derived & Oxygen (O) derived.

Parameter	***Parameter type***	***Description***	***Default value***
ctHb	M	Concentration of total hemoglobin	9.3087 mmol/L(15.00 g/dL or 150g/L)
sO2	M	Oxygen Saturation	
FO2Hb	M	Fraction of oxyhemoglobin	
FCOHb	M	Fraction/(%) of carboxyhemoglobin in total hemoglobin in blood	0.004/ (0.4 %)

FMetHb	M	Fraction/(%) of methemoglobin in total hemoglobin in blood	0.004/ (0.4%)
T	Input	Patient temperature	37.0 °C (98.6 °F)
Temperature	Input	Ambient temperature	25.0 °C (77 °F)
FO2(I)	Input	Fraction/ (%) of oxygen in dry inspired air	0.21 (21.0 %)
RQ	Input	Respiratory quotient, ratio between the CO2 production and the O2 consumption	0.86
pH	M / ABD	pH of blood at patient temperature	
pCO2	M / ABD	Partial pressure (or tension) of carbon dioxide at patient temperature (mmHg)	
cHCO3-	ABD	Concentration of hydrogen carbonate in plasma (also termed actual bicarbonate)	
SBE	ABD	Standard Base Excess, an *in vivo* expression of base excess [3,4,5]. It refers to a model of the extracellular fluid (one part of blood is diluted by two parts of its own plasma) and is calculated using a standard value for the hemoglobin concentration of the total extracellular fluid.	
pO2	M / OD	Partial pressure (or tension) of oxygen at patient temperature (mmHg)	

Calculation of Derived Parameters

Unless otherwise stated, a derived parameter will be calculated or estimated irrespective of the sample type selected on the **Patient identification** screen:

- Arterial
- Capillary
- Venous
- Mixed venous
- Not specified

Some parameters, however, are defined for arterial or capillary samples only; they will be calculated only for sample types entered as “Arterial” or “Capillary”.

The equations for derived parameters are different from that of previous Radiometer analyzers. The calculation is done in accordance with NCCLS (CLSI)-approved guidelines. Lists of equations can be found in the IFU on the shared drive or in hard copy form in the PFT lab.

General Sampling Procedure

IMPORTANT: GLOVES MUST ALWAYS BE WORN WHEN OBTAINING OR ANALYZING BLOOD SAMPLES.

Syringe Sample:

1. Log into analyzer
2. Check that the ABL90’s status traffic light is displaying green or yellow light.
3. Touch screen *Syringe*- Verify in Syringe mode - Aspiration screen appears.
4. When prompted, push sample on inlet probe until aspiration begins, and hold until screen highlights to remove sample.
5. Scan barcode on patient label and enter all patient data

Patient ID (MRN), Patient Name, DOB, Site, height, weight, and FiO2 is required information for ABL90 to process sample. A new sample may be introduced when the screen displays green tabs.

Proficiency Testing

To ensure accurate and precise testing, the laboratory utilizes the Survey Program of the College of American Pathologists (CAP). A proficiency test is a process that lets

a lab verify the performance of an analyzer with accredited test solutions. As part of the CAP accreditation program, the laboratory performs required quarterly proficiency testing. See policy 04-09 for further information on proficiency testing in the lab.

Downtime

If the blood gas analyzer is "down" due to maintenance or other reasons and a patient sample needs to be analyzed, the Pulmonary Function Laboratory has an agreement with the Department of Pathology Clinical Chemistry Laboratory to run samples in the Emergency Department (ED), as necessary. The Therapist/Technician should call the Laboratory and inform the Supervisor of the need.

Values & Ranges

The ABL 90 FLEX PLUS reportable and indication ranges that define the analyzer's measurement capabilities are listed in the manufacturer's IFU. These ranges have been applied to assist in defining the reference ranges for patient sample reporting.

Reference Ranges/ Normal Values:

Parameter	Expected Values for Parameters	
	Male	Female
pH	7.35 - 7.45	7.35 - 7.45
pCO2 (mmHg)	35 - 48	32 - 45
pO2 (mmHg)	80 - 100	80 - 100
ctHb (g/dL)	13.5 – 17.5	12 – 16
sO2 (%)	95 - 99	95 - 99
FO2Hb (%)	94 - 98	94 - 98
FCOHb (%)	0.5 – 1.5	0.5 – 1.5
FMetHb (%)	0 – 1.5	0 – 1.5
HCO3 (mmol/L)	22 – 26	20 – 24
SBE (mmol/L)	-2.4 - +2.3	-3.3 - +1.2

Reporting Results: Values falling outside of the above set reference ranges will be noted by the therapist performing the test, reviewed for critical values, and reported to the ordering physician.

Results will be reported, in the units described above, on the Pulmonary Function Final Report for those patients receiving routine pulmonary function studies. Special requests for blood gases will be reported in the same manner, although the requesting physician will be called by phone or radio pager and informed of the results immediately.

Critical or Panic Values: Please see Notification of Physician of Critical Level Results policy (Policy 04-07, Test Data).

Below are the listed reported parameters and the critical levels for each.

pH	<7.30 or >7.50	Hbg	</=8 or >17

pCO2	>55	HbCO%	>5%
pO2	<60	MetHb%	>2%

Limitations The manufacturer recommends to only analyze heparinized and electrolyte-balanced human whole blood samples or dedicated quality control material.

In Vivo Interferences: No substances in normal blood will interfere with pH and pCO2 measurements. Blood from patients anaesthetized with nitrous oxide or halothane may give unreliable pO2 values due to the influence of these anesthetic gases on the pO2 electrode.

A therapist must always interpret patient test results in the relevant clinical context. A chart review is required on each patient that is being tested. If the Therapist discovers, through chart review, that an interfering substance is present, this information will be documented on the patient report.

References

Davidsohn, I., M.D. and Henry, J.B., M.D.: Todd-Sandford Clinical Diagnosis by Laboratory Methods. Philadelphia: W.B. Saunders Co. 15th Ed. (1974).

Instructions for Use Manual for ABL90. Radiometer Medical ApS (2020).

Shapiro, B.A., Harrison, R.A., Walton, J.R.: Clinical Application of Blood Gases. Chicago: Year Book Medical Publishers Inc. 2nd Ed. (1980).

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 Function Laboratory** **Changes to policy**	
4/14	**A. Duarte, MD** **Changes to Policy**	
7/16	**A. Duarte, MD** **Changes to Policy**	
11/17	**A. Duarte, MD** **No changes to Policy**	

10/19 **A. Duarte, MD**
No changes to Policy

8/21 **A. Duarte, MD**
No changes to Policy

9/22 **A. Duarte, MD**
Changes to Policy

9/23 **A. Duarte, MD**
No changes to Policy