OLIVE VIEW-UCLA MEDICAL CENTER
RESPIRATORY CARE SERVICES – ABG LABORATORY
POLICY & PROCEDURE

NUMBER: 5525
VERSION: 1

SUBJECT/TITLE: **BLOOD GAS LABORATORY QUALITY CONTROL / QUALITY ASSESSMENT**

POLICY: The Blood Gas Laboratory verifies tests, methods, and instruments in order to establish quality control procedures. QSA.02.01.01

PURPOSE: The purpose of the Blood Gas Laboratory Quality Assurance/ Quality Control (QA/QC) program is to establish quality control procedures. The (QA/QC) program will include:

- verify the accuracy
- prove precision
- establish reportable ranges
- document verification

This document is to be used by the Blood Gas Laboratory Testing personnel as a reference guide to ensure all data reported from this lab is of the highest quality as possible.

DEPARTMENTS: **RESPIRATORY CARE SERVICES**

DEFINITIONS:

PROCEDURE: **The Blood Gas Laboratory verifies tests, methods, and instruments in order to establish quality control procedures. QSA.02.01.01**

The Blood Gas Laboratory performs calibration and recalibration. QSA.02.02.01

The OVMC Blood Gas Laboratory must perform calibrations on the Siemens Rapid Point 500 blood gas instrument based upon manufacturer's recommended practices. The calibration procedures will include but not limited to the following:

- **1&2 point calibration** The Rapidpoint 500 is programed to perform 1 point calibration every 30 minutes and a 2 point every 2 hours. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800 255-3232) to correct the deficiency.
- **3 level quality control** The Rapidpoint 500 has an Auto QC system which is programed to perform one 3 of different levels quality control every 8 hours. The 3 level QC program must be recorded in the Rapidcom data management system and reviewed on a daily basis. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-

support must be contacted (800 255-3232) to correct the deficiency. All corrective actions taken must be documented in the QC Corrective Action Log Book.

- **External quality control** 3 level external QC testing must be performed every 24 hours. Each one level every 8 hours. The testing material is Siemens Rapid QC complete level 1, 2, 3. All internal and external QC test results must fall within Blood Gas Laboratory's established ranges. All printed QC results will be placed into the external QC log book and reviewed and signed off by the Blood Gas Lab Director or designee. Any analytes that fails to fall within the Blood Gas Laboratory's established ranges is considered out of control and the instrument cannot be utilized for specimen processing. Corrective action must be initiated based upon manufacturer's guidelines found in the Rapidpoint 500 operator's manual. The above outline task for the Rapidpoint 500 measurement cartridge will apply for the Auto QC cartridge as well. All test parameters of the external testing program must pass in order to process blood gas specimens. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800 255-3232) to correct the deficiency. All corrective actions taken must be documented in the QC Corrective Action Log Book.
- **External quality control testing after M/AQC cartridge changes** The Rapidpoint 500 has a measurement cartridge which has a 28 days or 420 samples life span whichever comes first. Once the measurement cartridge has been replaced, the internal quality control completed, 3 level external QC testing (using Siemens Rapid QC Complete level 1, 2, and 3) must be performed prior to specimen processing. All printed QC results will be placed into the external QC log book and reviewed and signed off by the Blood Gas Lab Director or designee. External QC results will be up-loaded into the RapidComm data management system. The testing material is Siemens Rapid QC Complete level 1, 2, 3. All internal and external QC test results must be within ranges. Any analyte that fails to fall within Blood Gas Laboratory's established range is considered out of control and the instrument cannot be utilized for specimen processing. Corrective action must be initiated based upon manufacturer's guidelines found in the Rapidpoint 500 operator's manual. The above outline task for the Rapidpoint 500 measurement cartridge will apply for the Auto QC cartridge as well. All test parameters of the external testing program must pass in order to process blood gas specimens. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800 255-3232) to correct the deficiency. All corrective actions taken must be documented in the QC Corrective Action Log Book.

The Blood Gas Laboratory performs calibration verification.QSA.02.03.01

- Calibration Verification Program (CVM) Siemens CVM Cat: 116189 The CVM program is a biannual testing program utilizing 5 known levels of a formulated material measuring blood gas, electrolytes, total hemoglobin and metabolite. The resulted data will be reviewed and determined to be with in published manufacturer's ranges and plotted on a linearity graph.
- The Analytical Measurement Range (AMR) will establish the reportable ranges (high, low) with in each Rapidpoint 500 Blood Gas instrument. In the event of a failure immediate on site remedial action must be taken or Siemens Tech-support must be contacted (800 255-3232) to assist in the corrective action. All corrective actions taken must be documented in the QC Corrective Action Log Book.
- Calibration verification is performed whenever the following events occur:
  a. A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
  b. Major preventive maintenance is performed, or critical parts are replaced that may influence test performance.
  c. Quality control results indicate that there may be a problem with the test system.
  d. An environmental change occurs, including instrument relocation.
  e. An instrument has been replaced.
  f. Quality control materials reflect an unusual trend or shift or are outside the laboratory's acceptable limits, and other means of assessing and correcting unacceptable quality control values fail to identify and correct the problem.

The Blood Gas Laboratory has its own quality control ranges with valid statistical measurement for each test. QSA.02.07.01

- Prior to initiating new quality control lot the Blood Gas Laboratory will establish quality control limits based upon manufacturer's insert.
- The laboratory determines through repetitive testing of 15 to 20 results per level of Siemens Rapid QC Complete level 1, 2, 3 the statistical parameters for each lot number of control material, including mean, standard deviation, and coefficient of variation. The parameters are documented.
- A manufacturer's control range may be used if the laboratory can verify that the mean the laboratory obtained falls within the manufacturer's ranges. The verification is documented.
- The laboratory establishes statistical parameters for unassayed control materials over time through concurrent testing of control materials with previously determined statistical parameters. The established statistical

parameters are documented.

The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations. QSA.02.08.01

- The Blood Gas Laboratory will conduct correlation studies every 6 months which will include different methodologies or instruments and or different locations. Correlation studies will be performed during the months of June and December of every year.
- The Blood Gas Laboratory will perform correlation at least once every 6 months the correlations will be documented. Correlation studies will be performed during the months of June and December of every year. A comparison between instruments by calculating the percentage of difference which should be less than or equal to 10%.
- The correlation studies will be conducted between blood gas analyzer to blood gas analyzer and to the core laboratory.

The laboratory performs quality control testing in the same manner as it performs patient testing. QSA.02.09.01

- Only staff who perform patient testing perform quality control testing.
- Staff who perform patient testing test quality control materials in the same manner as they test patient specimens.
- The laboratory rotates quality control testing among staff who perform patient testing.
- Note: Not all staff are required to perform quality control testing each day they perform patient testing, but all staff are included in the quality control testing over time.

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process. QSA.02.10.01

- The Blood Gas Laboratory performs 2 types of quality control methodologies. The first is the internal automated QC system that performs 1 of 3 level QC testing every 8 hours. The second is external QC testing which requires the blood gas testing staff member to perform 1 of 3 level QC testing every 8 hours. Both testing systems require documentation. The QC material is based upon recommendation of the Siemen Health Diagnostics Inc.
- The laboratory does not report individual patient results unless quality control criteria are met.
- The laboratory does not report individual patient results that exceed the reportable range.
- The laboratory performs quality control testing before resuming patient testing when the following occurs:

a. A change of the measurement and or automatic quality control cartridges.
b. Major preventive maintenance or replacement of critical parts that may influence test performance.
c. After calibration in order to verify that the calibration protocol was successful. The quality control results are documented.

The laboratory conducts surveillance of patient results and related records as part of its quality control program. QSA.02.11.01

- The Blood Gas Laboratory assigned testing personnel each day:
  a. Review all blood gas results entered into ORCHID for completeness and accuracy.
  b. Review QC data on the Rapidcom system.
  c. Review external QC data and log book for completeness.
  d. Review temperature log for completeness

The laboratory investigates and takes corrective action for deficiencies identified through quality control surveillance. QSA.02.12.01

- The Blood Gas Lab must monitor any potential and actual preanalytical, analytical, post analytical deficiencies:
- In the event of a blood gas instrument failure either QC or hardware the Blood Gas Lab has a total 4 instrument available for specimen processing.
- The laboratory follows its policies and procedures to monitor, assess, correct and document problems identified in preanalytic, analytical, and postanalytic processes.
- The laboratory performs corrective action when the following situations occur:
  a. Quality control results do not meet the laboratory's criteria for acceptability.
  b. An instrument does not meet function check or performance testing requirements.
  c. Incidents of incorrect test results are reported.
  d. Patient test results are reported outside of the laboratory's reportable range of test results.
  e. Criteria for proper storage of reagents and specimens are not met.
  f. Other incidents of unsatisfactory specimen collection, testing, or reporting are identified.
  g. The corrective action is documented. (See also QSA.02.04.01, EP 8)
- For each quality control result outside acceptable limits, the laboratory conducts an investigation of all potential causes, provides evidence of review, and takes corrective action. These activities are documented. (See also QSA.02.04.01, EP 8)
- For each quality control result outside acceptable limits, the laboratory

takes corrective action before patient testing is resumed. (See also QSA.02.04.01, EP 8)

- In the event of a corrective action the Blood Gas Lab must document the following:
  a. As related to quality control results
  b. As related to repeat patient testing
  c. As related to correction of individual results
  d. (see QSA.02.04.01 EP8
- Blood Gas Lab corrective action will perform the following :
  a. Review effectiveness of corrective action
  b. Review and possible revision of policy & procedures to prevent recurrence
  c. Discuss the investigation, corrective action and possible changes in procedure(s) with affected staff
  d. (see QSA.02.04.01 EP8)
- In the event the Blood Gas Lab becomes aware of an incorrect result reported. The lab must notify the Licensed Patient care giver (attending Physician or RN) and document the name, date, and time.
- The lab will issue a corrected report to the attending Physician as soon as the test results become available.
- In the event of an incorrect result the lab will retain the original documents along with the corrected reports.

The laboratory stores, prepares, evaluates, and tracks reagents. QSA.02.13.01

- The Blood Gas Lab will maintain storage of Measurement, AQC, Wash/Waste Cartridges, Rapid QC complete, CVM, and PT testing materials based upon manufacture standards.
- The Lab will store all consumables in accordance manufacture labeling.
- The lab will document the external QC material lot number into the Rapidcom Data management system.
- The laboratory does not interchange components of reagent kits of different lot numbers unless permitted by the manufacturer.
- The laboratory uses kits, reagents, media, and supplies according to manufacturers' specifications. (See also QSA.02.14.01, EP 5)

The laboratory labels reagents and solutions completely and accurately. QSA.02.14.01

- The Siemens Measurement, AQC, Wash/Waste Cartridges, Rapid QC complete, CVM, and PT testing materials must have an expiration date.
- The laboratory identifies reagents that could pose a hazard for staff safety.
- The laboratory does not use expired reagents or solutions. (See also QSA.02.13.01, EP 8)
- The laboratory follows its policies and procedures for labeling reagents and solutions.

The laboratory verifies each clinical chemistry test system through the use of quality control materials. QSA.06.01.01

- Please refer to The Blood Gas Laboratory performs calibration and recalibration. QSA.02.02.01
  a. 1&2 point calibration
  b. The Q8 AQC/External QC program

The laboratory verifies the operation of each blood gas testing instrument through the use of quality control materials. QSA.06.02.01

- The laboratory tests at least three levels of quality control materials (acid, normal, alkalosis) for blood gas testing each day the procedure is performed. The quality control results are documented.
- The laboratory tests at least one level of quality control material for each eight hours of patient blood gas testing. The quality control results are documented. Note: The laboratory should attempt to perform quality control testing as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before or after the 8-hour mark, providing a 30-minute window. Ranges in excess of +/- 30 minutes that produce a window of more than an hour do not meet the intent of this element of performance.
- The laboratory tests at least one level of quality control material each time patients are tested unless automated instrumentation verifies calibration internally every 30 minutes.
- In the event that a QC test is missed, no patient specimen should be reported till a successful QC test has been performed.

Approved by: Jeanne Wallace (Division Chief), Joe Keys (Assistant Hospital Administrator)	Date: 10/28/2016
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