Personnel performing arterial punctures are trained in the recognition and management of possible complications of this procedure.

Evidence of Compliance:

✓ Records of training in personnel files

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.

***REVISED** 12/26/2024*

CHM.33900 Collateral Circulation — Phase II

For radial artery sampling, a test for collateral circulation is performed before arterial puncture if clinically indicated, with results recorded.

NOTE: Any of the various technologies evaluated in the published literature are acceptable. Consensus should be established between the laboratory and involved clinicians to define situations that require testing for collateral circulation, if any, to potentially avert patient injury.

Evidence of Compliance:

✓ Records of collection site and results of applicable collateral circulation testing

REFERENCES

1) Vaghadia H, *et al*. Evaluation of a postocclusive circulatory hyperaemia (PORCH) test for the assessment of ulnar collateral circulation. *Can J Anaesth.* 1988;35:591-598
2) Cheng EY, *et al*. Evaluation of the palmar circulation by pulse oximetry. *J Clin Monit.* 1989;5:1-3
3) Levinsohn DG, *et al*. The Allen's test: analysis of four methods. *J Hand Surg.* 1991;16:279-282
4) Fuhrman TM, *et al*. Evaluation of collateral circulation of the hand. *J Clin Monit.* 1992;8:28-32
5) Furhman TM, *et al*. Evaluation of digital blood pressure, plethysmography, and the modified Allen's test as a means of evaluating the collateral circulation to the hand. *Anaesthesia.* 1992;47:959-961
6) Fuhrman TM, McSweeney E. Noninvasive evaluation of the collateral circulation to the hand. *Acad Emerg Med.* 1995;2:195-199
7) O'Mara K, Sullivan B. A simple bedside test to identify ulnar collateral flow. *Ann Intern Med.* 1995;123:637
8) Starnes SL, *et al*. Noninvasive evaluation of hand circulation before radial artery harvest for coronary artery bypass grafting. *J Thorac Cardiovasc Surg.* 1999;117:261-266
9) Cable DG, *et al*. The Allen test. *Ann Thorac Surg.* 1999;67:876-877

CHM.34000 Ambient Air Contamination — Phase II

The laboratory has a process to prevent ambient air contamination of blood gas samples before analysis.

REFERENCES

1) Ishikawa S, *et al*. The effects of air bubbles and time delay on blood gas analysis. *Ann Allergy.* 1974;33:72-77
2) Mueller RG, *et al*. Bubbles in samples for blood gas determinations. *Am J Clin Pathol.* 1976;65:242-249
3) Madiedo G, *et al*. Air bubbles and temperature effect on blood gas analysis. *J Clin Pathol.* 1980;33:864-867
4) Biswas CK, *et al*. Blood gas analysis: effect of air bubbles in syringe and delay in estimation. *Brit Med J.* 1982;284:923-927
5) McKane MH, *et al*. Sending blood gas specimens through pressurized transport tube systems exaggerates the error in oxygen tension measurements created by the presence of air bubbles. *Anesth Analg.* 1995;81:179-182
6) Astles JR, *et al*. Pneumatic transport exacerbates interference of room air contamination in blood gas samples. *Arch Pathol Lab Med.* 1996;120:642-647
7) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.

BLOOD GAS INSTRUMENTS

Inspector Instructions:

	• *Blood Gas analysis policy and procedure* • *Sampling of blood gas calibration records* • *Sampling of blood gas QC records*
	• *Is any testing performed on specimen types that are not FDA-cleared/approved on the blood gas instrument?*
	• *Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action*

CHM.34200 Calibration Materials — Phase II

The materials used for calibration of the pH, CO_2, and O_2 sensors are either in conformance with the instrument manufacturer's specifications or traceable to NIST Standard Reference Materials.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Blood Gas and pH Analysis and Related Measurements; Approved Guideline - Second Edition*. CLSI document C46-A2 (ISBN 1-56238-694-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2009.

CHM.34300 Calibration - Blood Gas Instruments — Phase II

Blood gas instruments are calibrated according to manufacturer's specifications and at least as frequently as recommended by the manufacturer.

NOTE: Some instruments have built in calibration that is performed automatically by the instrument; however, there must be some defined procedure for verifying the reliability of this process. If appropriate, the calibration must compensate for the influence of barometric pressure.

Evidence of Compliance:

✓ Records for calibration at defined frequency

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3709 [42CFR493.1267(a)]

CHM.34400 Daily QC - Blood Gas Instruments — Phase II

A minimum of one level of quality control for pH, pCO_2 and pO_2 is analyzed at least every eight hours of operation when patient specimens are tested, or more frequently if specified in the manufacturer's instructions or laboratory procedure, and when changes occur that may impact patient results.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed. Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, or change of a critical instrument component, or with software changes, as appropriate.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

Evidence of Compliance:

- ✓ Records of QC results including external and internal control processes **AND**
- ✓ Manufacturer product insert or manual

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24) [42CFR493.1267(b)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

CHM.34500 Daily QC - Blood Gas Instruments — Phase II

The control materials for pH, pCO_2 and pO_2 represent both high and low values on each day of patient testing.

NOTE: If using internal controls, the electronic simulators should challenge at high and low values.

Evidence of Compliance:

- ✓ QC records reflecting the appropriate use of controls

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24) [42CFR493.1267(b)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Ng VL, *et al*. The rise and fall of i-STAT point-of-care blood gas testing in an acute care hospital. *Am J Clin Pathol.* 2000;114:128-138

CHM.34600 QC - Blood Gas Instruments — Phase II

At least one level of quality control material for pH, pCO_2 and pO_2 is included each time patient specimens are tested, except for automated instruments that internally calibrate at least once every 30 minutes of use.

NOTE: An internal quality control process (eg, electronic/procedural/built-in) may be used to meet this requirement if an individualized quality control plan (IQCP) has been approved by the laboratory director.

Evidence of Compliance:

- ✓ QC results **OR** record of internal calibrator

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24): 3709 [42CFR493.1267(c)]
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.