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Applicability	Taylor + Trenton + Wayne

Quality Control Review and Peer Group Analysis

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document outlines the quality control review process. The first review is by the technologist performing the testing and then results are submitted to Bio-Rad, Aqure, or Stanbio for peer group review. In the peer group review, quality control data are objectively compared to other laboratories using the same methodologies, instruments, reagents and control material. A sophisticated method coding system allows accurate and meaningful peer group comparisons. End-of-cycle reports provide the laboratory with an overview of laboratory performance for Coefficient of Variation Index (CVI) and Standard Deviation Index (SDI) for the month. The Aqure software performs comparisons based on mean bias and Coefficient of Variation percent (CV%).

Qualitative QC is reviewed for acceptability by the technologist performing the testing. Results are documented on the patient log or QC log and are reviewed at least monthly.

II. PROCEDURE:

A. Bio-Rad Unity Real Time program for Bio-Rad controls and instruments with Quality Control Data Programs with summarized data.

1. Quality Control Review tab on the instrument is examined for failed QC results. Control Values are then evaluated on the instrument via the Levey-Jennings tab. (see ~~Troubleshooting Quality Control in Chemistry procedure~~Chemistry Quality Control and Run Acceptance Criteria). Once released from the instrument, QC values are also evaluated using BioRad Unity Web program. The tech performing patient testing will log into Unity Web and review the daily QC and document the action taken on any

outliers.

2. Lead Medical Technologist or designee performs Supervisor Review at least monthly. Laboratory data collected in Bio-Rad Unity Real Time is submitted before the 7th day of the following month for peer group analysis.
3. Laboratory Manager, Lead Medical Technologist, or designee reviews monthly data for the designated time period. Any CVI or SDI failures will be investigated.

B. Radiometer Aqure Software for Radiometer Blood Gas Analyzers.

1. Control values are stored in the instrument CPU which is capable of handling multiple lots for the same level. When a new lot is about to be started, it is assigned a QC slot, the ranges are scanned in from the package insert, and it is added to the QC automatic schedule after the new lot of QC has been verified.
2. Blood gas QC is evaluated at the beginning of each shift by the tech performing the testing. Depending on the site, QC is reviewed and documented in Bio-Rad Unity Real Time, QC log sheets, or directly into the analyzer by each shift. QC data is automatically downloaded from the instruments to the Aqure program. Monthly, an Aqure peer comparison report is pulled for statistical analysis and peer group comparisons. Any peer messages indicating a failed mean bias or CV% must be investigated.
3. Laboratory Manager, Lead Medical Technologist, or designee reviews monthly cumulative data for the designated time period. Any mean bias or CV% failures will be investigated.

C. Betahydroxy-butyrate (BHOB) QC is captured into Bio-Rad Unity Real Time for review by the tech performing the testing. Monthly, the mean and SD are manually entered into the Stanbio Laboratory Quality Assurance Network website for peer group and statistical evaluation for SDI and CVI.

1. Quality Control Review tab on instrument is examined for failed QC results. Control Values are then evaluated on the instrument via the Levey-Jennings tab. Refer to ~~Troubleshooting Quality Control in Chemistry Procedure~~Chemistry Quality Control and Run Acceptance Criteria. Once released from the instrument, QC values are also evaluated using Bio-Rad Unity Web program. The tech performing patient testing will log into Unity Web and review the daily QC and document the action taken on any outliers.
2. QC Summary Data is printed from the instrument and entered into the Stanbio Laboratory Quality Assurance Network website. Any CVI or SDI failures will be investigated
3. Laboratory Manager, Lead Medical Technologist, or designee reviews monthly cumulative data for the designated time period.

D. Qualitative QC is run with each patient run or according to the test's IQCP (Individualized Quality Control Plan) if one has been established. The QC is reviewed for acceptability and is documented on the patient log or the QC log at the time of testing. In addition, the QC is documented in the Laboratory LIS when applicable.

1. Documented Quality Control results are reviewed by the Laboratory Manager, Lead

Medical Technologist, or designee at least monthly.

2. IQCPs are assessed monthly for QC failures or new risks that might require updating the IQCP.

Do not report any patient results for any analytes if the QC is not acceptable.

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	9/27/2024
Policy and Forms Steering Committee Approval (if needed)	Tanya Williams: Medical Technologist Lead	9/25/2024
	Christopher Ferguson: Dir, Lab Services	9/25/2024
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Applicability

Taylor, Trenton, Wayne