HEADS UP...

TOPIC: Performing correlation testing
***SETTING:* Laboratory Accreditation Program (LAB)**

Why is this important?

The requirements in the quality systems assessment chapter are designed to guide laboratories in achieving accuracy for nonwaived testing. As such, it is important to have processes in place that produce meaningful, reproducible, useful, valid, and dependable test results. Because the requirements address all aspects of quality system assessments, it is the responsibility of all staff working in the laboratory to support the quality system in place to ensure the best possible results and outcomes. Correlation testing is done to evaluate the results of the same test performed with different methodologies or instruments or at different locations. These should be performed every six months and documented. Correlation testing is one component of a general quality control testing program.

Scope of the Problem:

Time period: **January 1, 2019 – March 31, 2019**
Number of full surveys performed: **873**
Number of surveys with moderate to high-risk findings related to correlation testing (**QSA.02.08.01 EP 2**): **96 (11%)**

Observations identified within a specific topic area may reveal systemic areas for improvement across the organization. These improvement opportunities might be reflected in other chapters, standards or EPs. *See also CLIA §493.1281(a); §493.1281(c)*

Sample survey observations [from surveyor notes] and contributing factors

- The laboratory did not perform correlations at least once every six months between automated and manual differentials, or between the open and closed modes of the hematology analyzer.
- There was no evidence that correlations were performed for automated, gel and manual blood bank methods every six months.
- Method comparisons were not documented for two BacT/Alert instruments that both reported qualitative results.
- The laboratory had not performed and documented correlations between the two Nova blood gas analyzers every six months during the past two years for the blood gas analytes, pH, pO2, and pCO2. This was confirmed by the director of respiratory.
- The laboratory did not perform a 5-part manual to automated differential count correlation at least once every six months. The laboratory performed a correlation of Neutrophils, Lymphocytes, and Monocytes, i.e. 3-part, but there was no evidence of documentation that Basophils and Eosinophils were included in the correlations performed in the past 24 months.

Potential contributing factors:

- Lack of effective monitoring, accountability and oversight regarding who had responsibility for performing correlation testing
- Lack of staff training and education; annual competence assessment did not include nonwaived testing
- Incorrect, incomplete documentation

How to identify potential problems in your organization

Review policies, procedures and protocols

☐ Does the laboratory have written policies and procedures to perform correlations between analytes when the same analytes are tested using different methodologies or instruments or at different locations (See also QSA.01.03.01, EP 3)?

☐ Do the policies and procedures specify that correlation testing must be performed once every six months and must be documented?

☐ Do the policies and procedures outline statistical methods to assess data to determine if correlation exists?

Interview staff

☐ Have staff participated in annual competence assessments for each of the tests he or she performs?

☐ Is staff aware when they must perform correlation studies (e.g. when the same analytes are tested using different instruments)?

☐ Is staff aware of the interval (six months) required for correlation testing?

Assess your environment

☐ Are all tests identified in all locations so what needs to be correlated is identified?

☐ Are correlation studies performed when the same analytes are tested using different instruments?

☐ Do documentation logs and records reflect that correlation studies have been performed every six months? Is the information complete and accurate?

Evaluate implementation

☐ Review data sources such as quality control records, maintenance records, test results, and worksheets.

☐ Continually assess staff knowledge and comprehension of testing protocols by asking questions and by performing direct observation of test performance.

What are some resources that can assist in mitigating risks in these areas?

- Centers for Medicare & Medicaid Services (CMS), Clinical Laboratory Improvement Amendments (CLIA) Regulation and Federal Register documents. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents
- Clinical and Laboratory Standards Institute (CLSI) https://clsi.org/
- AABB Technical Manual http://www.aabb.org/Pages/default.aspx