

HEADS UP...

TOPIC: Proficiency testing record-keeping

SETTING: Laboratory Accreditation Program (LAB)

Why is this important?

Proficiency testing for nonwaived tests is important as it can help a laboratory verify the accuracy and reliability of its testing and validate the entire testing process. Laboratories are required to participate in Centers for Medicare and Medicaid (CMS)-approved proficiency testing programs for all regulated analytes. The goal of proficiency testing is to help produce test results that are meaningful, reproducible, useful, valid, dependable, and specific to the needs of the population served. Maintaining accurate records of proficiency testing and investigations, evidence of review, and corrective actions as a result of unacceptable tests are an integral part of a quality proficiency testing process.

***Note: COVID-19 caused a significant reduction in the number of surveys performed in the first half of 2020. As such, this Heads Up report is focused less on recent observations and more on inquiries and feedback we received during this time period. The information and resources provided are intended to help organizations as they navigate this difficult and unprecedented time. Please see [Clarification re: resuming survey activities](#) for more information.**

Scope of the Problem:

Time period of inquiries: **January 1, 2020 through September, 2020**

Relevant standard: QSA.01.02.01 EP 2 The laboratory maintains records of its participation in a proficiency testing program. See also COPs \$493.1230, \$493.851(c)(1), \$493.851(c)(1)

Sample survey observations [from surveyor notes]and contributing factors

- There was no investigation of proficiency results of 80% documented. For example, [Event] scored an 80% for vancomycin and TSH. The analytes were repeated, and the results were within acceptable limits. The conclusion was random error. At the time of survey, a review of the instrument printouts for the unsatisfactory analytes were not always repeated on the same chemistry instrument.
- The main laboratory had not investigated of all potential causes, provides evidence of review, and performed corrective action for a folate result. [Event] had a folate result that had lack of consensus among all laboratories participating in the proficiency testing event (score was ungraded).
- There was no investigation of proficiency results documented for [Event]. The CK score of "0% = Unsatisfactory (0/5)" was not evaluated.
- The evaluation of proficiency results not submitted was not documented.
- The evaluation of proficiency results submitted late was not documented.
- There was no evaluation of ungraded proficiency results.

Potential contributing factors:

- Current policy and procedure lacked specific details to assist with a thorough investigation of all potential causes, provide evidence of review and perform corrective action for PT failures.
- Leadership failed to ensure that an assigned staff member was in place to complete required proficiency testing and report results to the Laboratory Director.
- Inadequate training or education for staff who investigate proficiency testing failures.
- No documentation of results of investigation, causes, evidence of review or corrective action.

How to identify potential problems in your organization

Review your policies and procedures

Does the policy and procedures require an investigation of all potential causes, provide evidence of review, and require corrective action for the following:

- Individual unacceptable proficiency testing results
- Late submission of proficiency testing results
- Nonparticipation in the proficiency testing event (score is zero)
- Lack of consensus among all laboratories participating in the proficiency testing event

Are these investigations documented?

Is there evidence of corrective action for all the above?

Does the policy identify the three different proficiency testing statuses for nonwaived regulated analytes and which notifications and actions are required by The Joint Commission? Note: Proactively initiating contact with the Joint Commission proficiency test monitoring staff is specifically recommended in the most severe circumstance of Subsequent Unsuccessful status (definition: A cumulative event in which the laboratory had Unsuccessful proficiency testing status two times in the past five years) see: <https://www.jointcommission.org/standards/standard-faqs/laboratory/quality-system-assessment-for-nonwaived-testing-qa/000001683/>

Interview staff

Are staff educated in the need to participate in proficiency testing?

Are staff aware of the process to follow if they have unacceptable proficiency testing results?

Are staff aware that unacceptable responses will require investigation, corrective action, and documentation?

Evaluate your environment

Does the laboratory utilize a checklist or worksheet to ensure complete investigations and corrective action for failed proficiency testing is completed?

Are results of failed PT reviewed with the Laboratory Director?

Evaluate implementation

Have corrective actions for unacceptable PT results been sustained?

Are the results of PTs investigations reviewed by the Laboratory Supervisor, Manager and Director on a regular basis (determined by the date of required testing)? Is this review documented?

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

- Joint Commission proficiency testing notification requirements FAQ: <https://www.jointcommission.org/standards/standard-faqs/laboratory/quality-system-assessment-for-nonwaived-testing-qa/000001683/>
- Frequently Asked Questions about proficiency testing, including the list of regulated analytes for nonwaived testing, can be found in <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf>
- List of proficiency testing programs: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf>
- General Joint Commission proficiency testing webpage: <https://www.jointcommission.org/accreditation-and-certification/health-care-settings/laboratory-services/proficiency-testing/>