20-Proficiency Testing

Prepared by: Yusra Othman /Director/Supervisor-Chem **Date:** May/29/2024
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Reviewed by: Jordan Dillard **Date:** June 24 2024
signature/title

Approved by: Sanford N. Bauby, M.D /Chairman **Date:** July 9 2024
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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

Purpose

This procedure defines the responsibilities and describes the process of proficiency testing.

Scope

Applies to all proficiency testing performed by the laboratory.

Definitions

● **PT – Proficiency Testing** – Evaluation of participant (laboratory or individual) performance against pre established criteria by means of inter-lab comparisons using same method or/and instruments. The PT programs for clinical laboratories are called "external quality assessment" programs.

● **Alternative assessment** – A system for determining the reliability of laboratory experimentations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory or participation is not required by the accrediting organization.

● CAP-College of American Pathologists

- API-American Profeciency Testing

Policy

PT samples are NOT to be sent to any reference laboratory for analysis. Communication with other laboratories regarding PT results is prohibited.

PT samples from another laboratory will not be accepted for testing at this laboratory.

In the event PT samples designated for another laboratory are received, appropriate notification will be forwarded to relevant third-party accrediting organizations.

PT will be performed appropriately by competent staff in the normal workflow of samples.

All staff should take part of doing PT by rotation, the attestation page should be signed by laboratory director and testing person, and the return report should be sign by lab director, when all corrective action taken, should be sign by all laboratory testing personal

Procedure

1. Responsibilities

a. Director of Quality or Designee (General Supervisor)

i. Maintain an accurate activity menu that reflects the current list of analytes and tests performed. Proficiency testing and/or alternative assessment should be performed biannually.

ii. Identify an approved proficiency provider (For example CAP, API) with the capability of supporting each analyte, where available. With the Laboratory Director's approval, enrol the lab in an approved proficiency testing program. Authorize PT provider to release PT results to third-party accrediting bodies as required.

iii. For those analytes/tests where no commercially available approved proficiency testing is available, refer to the Alternative Performance Assessment section.

iv. Coordinate proficiency testing and ensure that the lab testing activities comply with the PT provider's requirements.

b. Laboratory Personnel:

Follow the instruction as per PT provider on how to handle, store, order of testing etc.

i. Once proficiency testing samples are received, process these samples into the routine laboratory workflow. Notify the Quality Director/Supervisor that PT samples have been received and the accession numbers/sample IDs that are assigned to these samples. Accession numbers/sample IDs are de-identified and not associated with patient name(s) and/or sample information.

ii. Process, prepare and analyse the PT samples in the same manner as patient specimens. Refer to the procedures and work instructions appropriate for the sample matrix and assays requested.

iii. Upon receipt of the PT score from the PT provider, review the results. Document the results of this review.

c. If PT scores are unacceptable, The General Supervisor should document the issue as a nonconformance on a Corrective Action Report form.

i. Initiate corrective action as per the Corrective and Preventive Action SOP and Perform problem investigation to determine the root cause of the unacceptable results.

ii. Determine the appropriate remedial action required to mitigate the problem. Determine the appropriate corrective action required to prevent recurrence of the problem. Review the corresponding calibration data, quality control data and patient results to verify the accuracy of the actual test performance for any analyte that is graded unacceptable. Record the results of the root cause investigation and any remedial/corrective actions on Corrective action form

iii. Review the acceptable results for the presence of any trends or bias which may indicate a problem. If the review indicates the potential for a problem, document such on the Corrective-Preventive Action Request form. Initiate preventive actions to prevent a future PT failure due to the presence of trends or bias. Refer to the Corrective and Preventive Action System Level Procedure.

iv. Ungraded PT challenges such as:

1. Results submitted after the cut-off date

2. Failure to submit results

3. Incorrect completion of the result

4. PT challenges that were not graded because of lack of consensus

5. All other ungraded PT results will be reviewed and documented. E.g compare the results with all mean or method mean..

v. The Director of Quality or Designee will document each round of proficiency testing. These records will include:

1. Copy of the attestation form signed by the Laboratory Director or Designee and the participating testing personnel

2. Reviews of the graded PT results

3. Corrective actions taken as a result of unsatisfactory PT scores

4. Preventative actions taken as a result of the presence of bias or trends in acceptable PT scores.

2. Alternative Performance Assessment

a. Laboratory Personnel

i. For those analytes/tests where commercially available CAP or non-CAP proficiency testing material are not available, perform alternative performance assessment twice per calendar year.

ii. Select patient samples OR verified standards or control material at known concentrations that contain the specific analytes to be submitted to a single CLIA certified reference laboratory for comparative testing, or comparison to appropriate peer groups of CLIA-certified laboratories, if available.

b. Quality Director or Designee (General Supervisor) Quality Assurance

i. Review the results of the testing, including the results from the reference laboratory, if applicable. Quantitative results within +/- 2 SD or <30% (whichever is greater) are graded as "acceptable". For qualitative results, acceptability will be based on expected result or peer group consensus. Qualitative results that are not concordant with the expected result or peer group consensus will be graded as “unacceptable”. If results are unacceptable, a Proficiency Testing Review Form must be completed on all unacceptable analytes. Results will be reviewed and monitored for trends and biases.

ii. For those analytes where contracting with another reference laboratory to perform the analysis is not feasible or possible, verified standards or control

material at known concentrations of the specific analytes will be tested by the laboratory and evaluated against the vendor/manufacturer specified target concentration.

iii. A Proficiency Testing Review Form must be completed on all unacceptable analytes

iv. Initiate corrective action using Corrective and Preventive Action SOP as a guideline. Perform problem investigation to determine the root cause of the unacceptable results

v. Determine the appropriate remedial action required to mitigate the problem.

vi. Determine the appropriate corrective action required to prevent recurrence of the problem. Record the results of the root cause investigation and any remedial /corrective actions

vii. Even if all PT are successful but the results of the 5 samples shows Bias of an average SDI not within +/- 2SDI, should be investigated to avoid persistence of the problem and possible failure on the coming survey. This should be investigated, corrected and documented

References

CAP all common checklist 2023
COLA accreditation manual 2022