COLLEGE of AMERICAN PATHOLOGISTS

Guidance Document

Topic: **Review of patient results in response to a PT failure**

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Objective: Provide guidance for laboratories and LAP staff to determine when review of patient results is necessary in response to an unsatisfactory, unsuccessful or critical proficiency testing (PT) failure.

Clerical error: Most clerical errors on PT samples will have a low risk of occurring when patient samples are tested. Laboratory investigation of patient results from the time of PT survey is optional and should be undertaken only when the laboratory believes that the clerical error may be reproduced or occur with patient samples.

Example 1: Laboratory submits PT results without necessary method, instrument or reagent code necessary for PT provider to grade survey.

Example 2: Laboratory technician transcribes result incorrectly onto PT form, when no manual transcription would have occurred with patient specimens.

Procedural: If the same procedure is used for both PT and patient samples, then PT failures resulting from procedural errors or issues must include investigation of selected patient results from the time of the PT survey until the procedural problem was detected and corrected. If the part of the procedure identified as responsible for PT failures is specific to testing of PT material, then no investigation is required.

Example 1: Laboratory investigation into PT failure reveals that technologists do not consistently follow procedure for addition of Coombs reagent during compatibility testing. Patient result investigation is warranted as the same procedural error could be made using patient specimens.

Example 2: Laboratory investigation into antibiotic susceptibility testing PT failures reveals that several techs are incorrectly measuring disk zone sizes. Patient investigation is warranted as the same procedural error was likely made using patient specimens.

Example 3: Laboratory investigation into coagulation PT failures reveals that technologists did not reconstitute or mix PT specimens according to PT provider instructions. No similar procedures are necessary for patient specimens. The laboratory may determine that no patient result review is warranted.

Analytical: Analytical PT failures must include investigation into the impact of issues identified on selected patient results reported around the time of the PT survey. It is important to consider that the analytical issue that caused the PT failure may have occurred prior to the PT survey. Selected patient results should be reviewed over an appropriate timeframe that begins when the failure occurred and continues until the analytical problem was detected and corrected.

Example 1: Investigation into chemistry PT failures reveals that calibration curves are unacceptable or being performed with outdated calibrators. Patient result review is necessary.

Example 2: Investigation into hematology PT failures for basophils reveals that inadequate instrument maintenance and cleaning led to falsely elevated basophil counts at low/normal values. Patient review is necessary to determine the impact on patient results.

PT material: PT failures related to matrix effects or other issues with PT material do not require patient result investigation. Note that laboratories must provide documentation from the PT provider for PT material issues.

Specimen handling: Most errors related to PT material or specimen handling are low risk to be reproduced with patient specimens. Laboratory investigation of patient results from the time of PT survey is optional and should be undertaken only when the laboratory believes that the specimen handling error may be reproduced or occur with patient samples.

Example: Laboratory investigation into blood gas PT failures reveals that technologists do not consistently use the recommended device to transfer PT sample to instrument, or that delay in PT sample handling impacted results. No similar device or handling delays are possible with patient samples. The laboratory may determine that no patient result review is warranted.

Other: Reasons for PT failures under "other" or "random" will be varied, and the laboratory should document why patient result review was or was not performed when using the "other" response as cause of PT failure.

Suggestions for reviewing the impact of PT failures on patient results:

- Re-test any preserved or stable patient specimens after correcting the issue that led to PT failure.
- Review selected patient results reported prior to the issue/problem being resolved, compared with results from the same patients (if available) just after resolution of the issue. This method is applicable to analytes/tests that are not expected to change rapidly and/or have low biologic variability.
- Review selected patient results from before the issue was resolved relative to diagnosis or information available in the medical record, to determine whether results are consistent with patient's condition, diagnosis or other laboratory values.
- For high volume quantitative tests or procedures, calculate mean or median patient results in the days or weeks before and after the issue was resolved. Laboratories may apply filters to remove outlier data prior to calculating mean or median values. This technique can also be applied to review of qualitative tests, looking at distribution of positive and negative results before and after the issue was corrected.
- Re-assay any stable PT material after resolution of the issue responsible for PT failures. Note that the magnitude of change in PT material does not always reflect the magnitude of change observed with patient samples.
- Review calibration curves or internal QC material from before and after the issue is resolved. Note that changes in QC may be smaller or larger than associated changes in patient specimen values.
- Review comparisons of your instrument/lab QC to any external QC peer groups, before and after the issue was detected. Note that changes in QC values do not always reflect changes in patient specimen values.