DIAGNOSTIC ACCREDITATION PROGRAM
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MEMORANDUM

To: Laboratory Medical Director, Administrative Directors, Quality Managers
Chief Technologists/Laboratory Managers/ Regional/Section Supervisors

From: Karin Kijek, Proficiency Testing/QC Specialist

Date: December 22, 2015

Re: Reporting Criteria and the PT Investigation and Exception Response Form

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Please ensure distribution to all relevant departments and individuals.

Please find below the criteria for reporting proficiency testing (PT) exceptions to the Diagnostic Accreditation Program (DAP), as well as information on filling out the PT Investigation and Exception Response Form.

The Laboratory Medicine Accreditation Standards (2015) include:

- **QUA2.3.2** PT results are monitored by the medical director within a defined time frame.
- **QUA2.3.3** Corrective actions are implemented when predetermined performance criteria are not fulfilled.
- **QUA2.3.7** Records of corrective action are submitted to the DAP where appropriate, within the required time frame.

Criteria for Reporting PT Exceptions to the DAP

Laboratories are required to document **all** PT results that exceed acceptable survey limits and take corrective action to prevent reoccurrence. However, only exceptions to mandated analytes/procedures that fit the criteria below, require submission of a PT Investigation and Exception Response Form to the DAP.

Bio-Rad PT Programs

1. Failure to report PT results for a testing event
2. Any analyte giving results greater than +/- 2.0 Z-score on three (3) consecutive testing events
3. Three (3) or more analytes on a given sample with results greater than +/- 2.0 Z-score on any given testing events

4. Any result greater than 3.0 Z-score
5. Any result exceeding the "truncation" limits by which Bio-Rad filters data

CAP/Oneworld Accuracy /WSLH/AAB/API

"Unacceptable results" fall outside the evaluation criteria, as defined by the PT Provider.

1. Failure to report PT results for a testing event
2. For programs with three (3) to five (5) samples per testing event:
    a. any single analyte with two (2) or more unacceptable results, in a single testing event
    b. any single analyte with one (1) or more unacceptable results on two (2) consecutive testing events
3. For programs with two (2) or less samples per testing event:
    a. any single analyte with an unacceptable result in a single testing event
4. Transfusion medicine and microbiology: any unacceptable result

Randox

1. Failure to report PT results for a testing event
2. A RMSDI of greater than +/- 1.5
3. Any analyte giving results greater than +/- 2.0 SDI on three (3) consecutive testing events
4. Three (3) or more analytes on a given sample with results greater than +/- 2.0 SDI on any given testing events
5. Any result greater than 3.0 SDI
6. Any gross outlier referred to by Randox as a "deactivated" result

IQMH

1. Failure to report PT results for a testing event
2. Any unacceptable result scored as A1, A2, A3

CMPT/cIQc/Other

1. Failure to report PT results for a testing event
2. Any unacceptable result

Ungraded or Educational Samples

The laboratory is responsible for performing a self-evaluation on all PT programs with results that are not scored or deemed "educational" by the PT provider. Results achieved by the laboratory are to be compared with the intended results given in the PT provider's summary. An internal investigation and corrective action should be undertaken for each exception. Submission of a PT Investigation and Exception Response Form to the DAP is **not** required.

Using the Investigation Response Form

The PT Investigation and Exception Response Form is periodically updated. Check for the most current version on the DAP website at http://www.dap.org/Default.aspx?p=171. When filling out this form online, the text spaces will expand as needed.

Analyte/Test

Please indicate the analyte or test that was flagged. In the case of many or all analytes flagged due to a **common** clerical, procedural or PT sample shipping problem (e.g. hemolysis due to freezing in transit), indicate this by checking the applicable box. It is not required to fill out a separate form for each analyte in this circumstance.

Attach Copy of PT Report/Supporting Documents

Attach a copy of the PT provider's report (i.e. the page with the flagged result) in order to provide necessary information such as results, peer groups, SDIs, and evaluation criteria. There is a checkbox under "Result Submitted" to serve as a reminder. Any other supporting documents related to the investigation, such as QC or instrument printouts, may be attached as well.

Repeated Tests

PT samples should be properly stored in order to repeat the analysis, if required. Repeat testing of the outlier sample should occur if the cause is unknown, or due to technical, equipment, method-related reasons, or problems with the PT material or vendor evaluation. Check the applicable box if unable to run a repeat, due to insufficient quantity or stability issues. Repeats are not required in the case of obvious clerical errors.

Evaluation of Patient Results in the Event of PT Exception

Patient data generated at the time of the PT exception must be reviewed to determine whether patient care was compromised; and if so, what follow-up is required. The medical director is responsible for defining this process.

Classifying the Problem

PT exceptions can fall into seven (7) main categories:

1. clerical
2. method
3. equipment
4. technical
5. PT materials
6. evaluation of results
7. no explanation after thorough investigation

Laboratories are required to classify the problem and report the conclusions and corrective actions on the PT Investigation and Exception Response Form. "No explanation after thorough investigation"

should **only** be chosen after all means of explaining the discrepancy have been exhausted and all possible explanations have been considered. It is the responsibility of the laboratory to investigate all discrepancies to the fullest extent possible.

Submission of the additional worksheets PT Investigation: Sources of Error (pages 1 and 2) and PT Investigation: Internal Review (page 3) is **optional**, provided that the problem has been explained as fully as possible on the PT Investigation and Exception Response Form. Please use the content of the checkbox pages as a guide to analyzing the problem and expanding on the explanation. The last page serves as an internal review checklist that likewise does not require submission to the DAP.

Root Cause Analysis

Root cause analysis is used as a review of PT performance and exceptions in order to identify the underlying causes. Classification of the PT exception in the categories listed above should be the first step in this process, followed by identifying areas for change, recommendations and sustainable solutions. Processes may need to be changed to improve laboratory systems and minimize the risk of reoccurrence. It may not be possible or necessary in every instance to identify the root cause; however, laboratories are encouraged to look beyond the surface in problem solving.

Documented examples of root causes associated with performance in PT events include the following:

- insufficient or ineffective training of staff
- lack of experience in, awareness of, or understanding of proficiency testing
- inadequate communication or instructions from supervisor
- use of inadequate and/or inappropriate equipment
- inadequate workplace design

Authorized Signatures

Please fill out the name and signature section at the bottom of the form. The laboratory medical director is only required to sign this form in response to a DAP request.

The DAP holds the laboratory medical director responsible for defining and monitoring standards of performance and ensuring the quality of results. The laboratory director must be advised of **all** proficiency test result deficiencies.

Submission of the Completed Investigation Form

Submission of the completed PT Investigation and Exception Response Form is required within **eight (8) weeks** of results receipt. For additional forms please visit the website at www.dap.org and go to Proficiency > Laboratory > [current year]. These forms can be filled out online and then printed for signatures and submitted.

The completed form may be submitted by mail, fax, or scanned and emailed to:

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