UC Davis Health
Sacramento, CA
Department of Pathology and Laboratory Medicine

HOW TO RESPOND TO A PROFICIENCY TESTING EXCEPTION

Administrative Procedure 701.A

PURPOSE

This procedure details the processes used by the Department to respond to Proficiency Testing Exception when needed.

PROCEDURE

1. A Proficiency Testing Exception Summary (PTES) is a packet of information that a PT participant will receive if the performance of an analyte or subspecialty falls below the Laboratory Accreditation Program's acceptable criteria for proficiency testing. The PTES packet includes instructions on how to respond to a PT exception, an Exception Response Form and a summary of scores for four PT testing events beginning with the current event and going back three events.

2. The laboratory must investigate the proficiency testing (PT) failure(s) and document the cause of the problem that led to the unacceptable PT result(s). The investigation and documentation should include:

    a) How the laboratory investigated the problem – a written summary of the steps the laboratory took to determine the nature of the problem.

    b) Written conclusion as to the cause of the unacceptable result(s).

    c) Specific corrective action (the changes the laboratory implemented) taken to prevent recurrence of the problem.

    d) Evidence (actions taken) that the problem was successfully corrected.

    e) Categorization of the reason for the unacceptable result(s) (Methodologic, Technical, Clerical, Problem with PT Material, Other, or No Explanation after Investigation).

    f) Evidence of the Medical Director's review of the investigation.

3. Each exceptional analyte and exceptional specialty/subspecialty require a response. Respond only to the results from the most recent period shown on the laboratory report. If the laboratory is no longer performing the test for which the PTES was generated, indicate such on the response and return it. **Failure to respond to an exception may jeopardize your laboratory's accreditation.**

EXCEPTIONS THAT REQUIRE A RESPONSE

For an analyte, specialty or subspecialty score that is **regulated** for proficiency testing by the Clinical Laboratory Improvement Amendments of 1988 and **reported** to the Centers for Medicare & Medicaid Services (CMS):

Please refer to Attachment A.

- The threshold for Immunohematology is 100% for ABO/RH and Compatibility testing.
- For proficiency testing in toxicology the reporting of a **false positive** on a drug screening test is considered unsatisfactory performance.
- For an analyte score that is **only reported** to the CAP's Laboratory Accreditation Program.

4. Instructions for completion of an exception response form are found on the reverse side of the exception response form.

   The Laboratory may either:

   - **Fax** the response to CAP at **847-832-8174**
   - **Email: ptcn@cap.org** (preferred method)

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Following are some common causes and appropriate action for this type of PTES:

Type	Cause	Appropriate action
General		
	The laboratory performs patient testing for the analyte or subspecialty in the year and event indicated but did not submit PT results.	State the reason laboratory did not submit PT results and the action taken to prevent recurrence.
Timing		
	The laboratory started testing for the analyte or subspecialty after the year and event indicated.	State the date laboratory enrolled in CAP-approved PT for the analyte or subspecialty.
Activity Menu maintenance		
	The laboratory no longer performs patient testing for the analyte or subspecialty indicated.	State the date that laboratory discontinued testing for the analyte or subspecialty. LAP activity menu will be updated to reflect this change.
	The laboratory does not perform patient testing for the analyte or subspecialty indicated.	State that laboratory does not perform patient testing for the analyte or subspecialty indicated. LAP activity menu will be updated to reflect this change.
PT enrollment		
	The laboratory was not enrolled in PT for the analyte or subspecialty in the year and event indicated.	State the date laboratory enrolled in CAP-approved PT for the analyte or subspecialty.
	The laboratory is enrolled in CAP-approved PT, but the LAP did not receive a score from the PT Provider for the analyte or subspecialty in the year and event indicated.	**Laboratory must instruct PT Provider to send its PT scores electronically to the LAP**. Attach the evaluated score from PT Provider for the analyte or subspecialty in the year and event indicated as proof of PT enrollment.
	The configuration of laboratory's PT result does not meet the PT requirements of LAP.	State the date laboratory enrolled in CAP-approved PT for the analyte or subspecialty.

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Type	Cause	Appropriate action
PT enrollment		
	The laboratory is enrolled in an Alternative PT Provider that has not been approved by the CAP.	Enrollment in CAP-approved PT is a requirement of the Laboratory Accreditation Program (LAP) for each analyte associated with a LAP identification number/CLIA number, when commercial PT is available. State the date laboratory enrolled in CAP-approved PT for the analyte or subspecialty.
PT Result not graded		
	The laboratory submitted PT results but the results were not graded for the analyte or subspecialty in the year and event indicated.	State the reason laboratory's PT results were not graded for the analyte or subspecialty in the year and event indicated and, if appropriate, the action taken to prevent recurrence. If unknown, contact PT Provider to determine the cause.
Clerical		
	The CAP number listed on laboratory's evaluation for the analyte or subspecialty in the year and event indicated is different than the LAP ID number listed on this PTES.	**Laboratory must instruct PT Provider to use the LAP ID number listed on this PTES to report laboratory's PT scores.** Attach the evaluated score from your PT Provider for the analyte or subspecialty in the year and event indicated as proof of PT enrollment.
	The laboratory submitted a PT result for a second instrument test but did not submit a result for a first instrument test.	The first instrument result should be obtained on the laboratory's **primary** instrument for performing that analyte. This means that all results reported as the first instrument may not be obtained on the same laboratory instrument. The LAP requires that a first instrument result be reported for all analytes when there is second instrument reporting option. The laboratory should provide the procedure that indicates the requirements for reporting PT results for first instrument testing.

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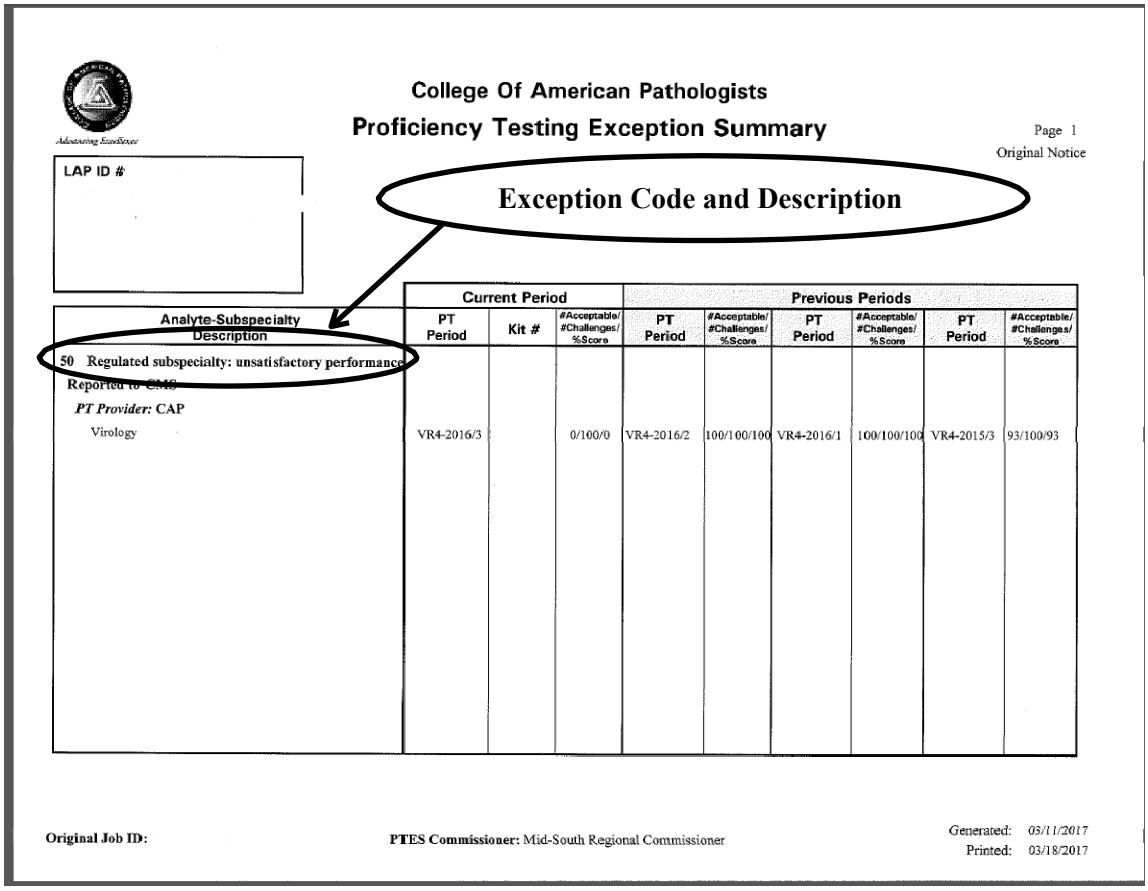
Type	Cause	Appropriate action
Clerical		
	The laboratory reported results for an analyte from a different kit and fulfillment group than what was indicated on the Analyte Reporting Selections (ARS).	The LAP monitors PT scores based on the ARS. If the laboratory reports results for a kit or group other than what has been chosen on the ARS, the PTES cycle will generate a PTES for the analyte in question. The laboratory must either make a change to the ARS by contacting their PT provider, or report results as indicated on the current ARS. Please forward documentation of intention as a response to this PTES.
	The laboratory reported Anti-HIV results using method two ("NOT for Regulatory Reporting - Screening Results Only") on the CAP Survey Test Result Form (TRF).	If your laboratory is reporting method two Anti-HIV on the CAP Survey TRF, this does not meet the CMS regulatory or the LAP PT requirements. Only method one results reported for Anti-HIV-1 screening and anti-HIV-1/2 will be used for regulatory purposes. Please respond to this PTES by: (1) attaching the method two evaluation from your PT Provider as proof of PT enrollment; (2) performing a self-evaluation of the results for this testing event by comparing the laboratory's method two evaluation results against method one results in the participant summary report; (3) confirming that the laboratory will report using method one on future proficiency testing reporting forms.
Methodology		
	Available CAP-approved PT is not compatible with the methodology used in laboratory.	Provide current documentation (dated within the past 12 months) from the reagent or instrument manufacturer.

Attachment- A PT Failure Exception Types and Codes

What do the exception codes mean on summary report?



1. Regulated Analyte – Reported to CMS

If laboratory receive a Proficiency Testing Compliance Notice (PTCN) with a "Regulated Analyte" exception type, the analyte is **regulated, and reported to CMS and the CAP Accreditation Programs**. PT score was less than 80% (or < 100% for ABO/Rh and Compatibility Testing).

Regulated Analyte (Reported to CMS) Exception Types		
Exception Code	**Exception Description**	**Action**
10	Regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
05	Regulated analyte: unsuccessful performance	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.

15	Regulated analyte: repeat unsuccessful performance	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing for 6 months.

2. Regulated Subspecialty – Reported to CMS

If laboratory receive a Proficiency Testing Compliance Notice (PTCN) with a "Regulated Subspecialty" exception type, the subspecialty is **regulated, and reported to CMS and the CAP Accreditation Programs**. PT score was less than 80%. These codes are applicable to testing in the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.

Regulated Subspecialty (Reported to CMS) Exception Types		
Exception Code	**Exception Description**	**Action**
50	Regulated subspecialty: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
58	Regulated subspecialty: unsuccessful performance	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
59	Regulated subspecialty: repeat unsuccessful performance	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the subspecialty. The laboratory may be required to cease testing for 6 months.

3. Regulated Analyte – Not reported to CMS

If laboratory receive a Proficiency Testing Compliance Notice (PTCN) with a "Regulated Analyte – Not reported to CMS" exception type, the analyte is **regulated but only reported to the CAP Accreditation Programs**. Usually this exception type indicates laboratory reported PT results for a regulated analyte from more than one PT product or kit. One PT result per analyte is required for each CAP number. PT score was less than 80% (or < 100% for ABO/Rh and Compatibility Testing).

Regulated Analyte (Not reported to CMS) Exception Types		
Exception Code	**Exception Description**	**Action**
20	Regulated analyte (not CMS reported): unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
25	Regulated analyte (not CMS reported): unsuccessful performance 2/3 events	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
26	Regulated analyte (not CMS reported): critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

4. Non-Regulated Analyte – Predictive Markers testing

If laboratory receive a PTCN with a "Non-Regulated Analyte" exception type for Predictive Markers testing, the analyte is **not regulated** and therefore **only reported to the CAP Accreditation Programs**.

PT was offered at 10 or 20 challenges
Laboratory score was less than 90%

Non-Regulated Analyte Exception Types – Predictive Markers testing		
Exception Code	**Exception Description**	**Action**
45	Non-regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. A response to CAP is required.
46	Non-regulated analyte: unsuccessful performance (2/3 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP. One event of alternative assessment is required.
48	Non-regulated analyte: critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

5. Non-Regulated Analyte – 5 challenges per mailing

If laboratory receive a PTCN with a "Non-Regulated Analyte" exception type, the analyte is **not regulated** and therefore **only reported to the CAP Accreditation Programs**.

PT offered at 5 challenges
Laboratory score was less than 80%

Non-Regulated Analyte Exception Types – 5 challenges		
Exception Code	**Exception Description**	**Action**
45	Non-regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
46	Non-regulated analyte: unsuccessful performance (2/3 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
48	Non-regulated analyte: critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

6. Non-Regulated Analyte – Less than 5 challenges per mailing

If laboratory receive a PTCN with a "Non-Regulated Analyte" exception type, the analyte is **not regulated** and therefore **only reported to the CAP Accreditation Programs**.

PT offered at 4 challenges
Laboratory score was less than 75%

Non-Regulated Analyte Exception Types – 4 challenges		
Exception Code	**Exception Description**	**Action**
39	Non-regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
40	Non-regulated analyte: unsuccessful performance (2/3 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
41	Non-regulated analyte: critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

PT offered at 3 challenges
Laboratory score was less than 67%

Non-Regulated Analyte Exception Types – 3 challenges		
Exception Code	**Exception Description**	**Action**
36	Non-regulated analyte: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
37	Non-regulated analyte: unsuccessful performance (2/3 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
38	Non-regulated analyte: critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

PT offered at 2 challenges
Laboratory score was less than 100%

Non-Regulated Analyte Exception Types – 2 challenges		
Exception Code	**Exception Description**	**Action**

33	Non-regulated analyte: unsatisfactory performance (2/3 events)	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
34	Non-regulated analyte: unsuccessful performance (3/4 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
35	Non-regulated analyte: critical performance (4/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

PT offered at 1 challenge
Laboratory score was less than 100%

Non-Regulated Analyte Exception Types – 1 challenge		
Exception Code	**Exception Description**	**Action**
30	Non-regulated analyte: unsatisfactory performance (2/3 events)	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
31	Non-regulated analyte: unsuccessful performance (3/4 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
32	Non-regulated analyte: critical performance (4/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

7. Forensic Toxicology Subspecialty

If laboratory receive a PTCN with a "Forensic Toxicology subspecialty" exception type, the subspecialty is **not regulated** and therefore **only reported to the CAP Accreditation Programs**. Laboratory's overall subspecialty score was less than 80%. Please note that score will be reflected as a zero on the PTCN summary report.

Forensic Toxicology Subspecialty Exception Types		
Exception Code	**Exception Description**	**Action**
60	Forensic Toxicology subspecialty: unsatisfactory performance	Investigate why the failure occurred and correct the problem. Keep documentation on file for next onsite inspection. A response to CAP is not required at this time.
65	Forensic Toxicology subspecialty: unsuccessful performance (2/3 events)	Thoroughly investigate the cause of the failure, correct the problem, and ensure patient results were not impacted. Submit documentation to CAP.
66	Forensic Toxicology subspecialty: critical performance (3/4 events)	CAP will send specific instructions to the laboratory on corrective action to take in order to continue testing the analyte. The laboratory may be required to cease testing.

8. Non-Participation in proficiency testing

If laboratory receive a PTCN with a "Non-Participation in proficiency testing" exception type, the following criteria apply:

- If the analyte is regulated, PT provider did not report a score to CMS.
- If the analyte is not regulated, PT provider did not report a score to the CAP Accreditation Programs.
- Non-participation in PT is equivalent to receiving a PT performance score of zero if performing the activity/test.
- Non-participation in PT is factored into the subsequent escalation of performance failures for the same activity/test.

Exception Types		
Exception Code	**Exception Description**	**Action**
98 or 99	Non-participation in proficiency testing	Investigate what caused non-participation in PT and correct the problem. Submit documentation to CAP.

REFERENCES

- Clinical and Laboratory Standards Institute (formerly NCCLS) guideline QMS 24: Using Proficiency Testing (PT) and Alternative Assessment to Improve Medical Laboratory Quality (2016).

- College of American Pathologists; PT Exception Types and Codes, May 2017

PROCEDURE HISTORY

Date	Written/Issued By	Revision/ Annual Review	Approved Date	Approved By
11/06	D. O'Sullivan	New	11/06	R. Green
11/07	D. Wright	Reviewed	11/07	R. Green
04/08	D. Wright	Reviewed	04/08	R. Green
4/09	D. Wright	Reviewed	4/09	L. Howell
4/10	D. Wright	Revised	4/10	L. Howell
04/12	T. Cox	Revised	04/12	J. Bishop
08/14	T. Cox	Biennial Review	08/14	L. Howell
08/16	E. Villadolid/ S. Okimura	Revised; Added Attachment A	08/16	L. Howell
08/18	N. Kaur	Revised & Merged Attachment A	08/18	L. Howell Via OnBase
08/20	N. Kaur	Revised	08/20	L. Howell Via OnBase