

What do the exception codes mean on my summary report?



College Of American Pathologists
Proficiency Testing Exception Summary

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Original Notice

LAP ID #

Exception Code and Description

Analyte-Subspecialty Description	Current Period			Previous Periods			
	PT Period	Kit #	#Acceptable/ #Challenges/ %Score	PT Period	#Acceptable/ #Challenges/ %Score	PT Period	#Acceptable/ #Challenges/ %Score
50 Regulated subspecialty: unsatisfactory performance Reported to CMS PT Provider: CAP Virology	VR4-2016/3		0/100/0	VR4-2016/2	100/100/100	VR4-2016/1	100/100/100
						VR4-2015/3	93/100/93

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Regulated Analyte – Reported to CMS

If you 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**. Your 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.

Regulated Subspecialty – Reported to CMS

If you 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**. Your 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.

Regulated Analyte – Not reported to CMS

If you 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 you 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. Your 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.

Non-Regulated Analyte – Predictive Markers testing

If you 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

Your 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.

Non-Regulated Analyte – 5 challenges per mailing

If you 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

Your 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.

Non-Regulated Analyte – Less than 5 challenges per mailing

If you 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

Your 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

Your 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

Your 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

Your 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.

Forensic Toxicology Subspecialty

If you receive a PTCN with a “Forensic Toxicology subspecialty” exception type, the subspecialty is **not regulated** and therefore **only reported to the CAP Accreditation Programs**. Your laboratory’s overall subspecialty score was less than 80%. Please note that your 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.

Non-Participation in proficiency testing

If you receive a PTCN with a “Non-Participation in proficiency testing” exception type, the following criteria apply:

- If the analyte is regulated, your PT provider did not report a score to CMS.
- If the analyte is not regulated, your 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.