


<b>Name of Policy:</b> <b>Proficiency Testing Protocol- Ungraded Exception Codes</b>		 <b>Effective date:</b> 2/3/2025 <b>Original effective date:</b> 4/2012	
<b>Policy Number:</b> 3364-136-CBGL-03			
<b>Approving Officer:</b> Medical Director, Blood Bank Program			
<b>Responsible Agent:</b> Director, Respiratory Care Services			
<b>Scope:</b> The University of Toledo Medical Center Respiratory Care Services Department			
Key words: Proficiency Testing, Protocol, Inspection, Diagnostic Procedure, Blood gas			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

The College of American Pathologists (CAP) uses exception codes that signify that the proficiency testing (PT) for an analyte has not been graded. The laboratory must identify all the analytes with an ungraded exception code and investigate the acceptability of performance.

(B) Purpose of policy

Assure consistent and proper functioning/verification of all clinical laboratory diagnostic procedures and analyses based on results obtained in assaying commercial unknown samples.

(C) Procedure

1. Initial review of proficiency results may be performed by Medical Director, Laboratory Coordinators, Laboratory Supervisors, Lead Technologists, and the Blood Gas Coordinator.
2. Medical Director, or designee will initial findings/notations, review results and sign entire report.
3. If an ungraded exception code is present, all the participant statistics are reviewed for any explanation. Investigation of the following codes include, but are not limited to:

<b>Code</b>	<b>Reason Code Description</b>	<b>Action Required</b>
11	Unable to Analyze	Documentation as to why not analyzed (i.e., instrument not functioning or reagents not available). Perform/document alternative PT for the period that commercial PT was not tested.
20	No appropriate target/response; cannot be graded	Documentation that the laboratory compared its results to the modal (most common) result.
21	Specimen problem	Documentation that the laboratory has reviewed the all-participant statistics supplied by the PT Provider. Perform/document alternative PT for the period that commercial Pt was not tested.
22	Result is outside the method/instrument reportable range	Documentation of the comparison of results to the all-participant statistics and peer group information supplied by the PT Provider.
24	Incorrect response due to failure to provide a valid response code	Documentation of the laboratory's self-evaluation of the results by comparing results to the all-participant statistics supplied by the PT Provider and corrective action of proper codes to use in the future.
25	Response not appropriate	Documentation of the investigation of the result as if it were an unacceptable result and review the all-participant statistics.
26	Educational challenge	Documentation that the laboratory has reviewed the all-participant statistics supplied by the PT Provider and, when indicated, corrective action is taken.
27	Lack of participant or referee consensus	Documentation that the laboratory compared its results to the modal (most common) result.
28	Response qualified with a greater than or less than sign; or, unable to quantitate	Documentation of the laboratory's self-evaluation of the results by comparing results to the all-participant statistics supplied by the PT Provider
30	Scientific Committee Decision	Documentation that the laboratory has reviewed all the participant statistics supplied by the PT Provider
33	Specimen determined to be unsatisfactory after contacting the CAP	Documentation that the laboratory has contacted the CAP, and no replacement specimens were available. Perform/document alternative PT for the period that commercial PT was not tested.
40/41	Results from kit not received or results received after evaluation date	Documentation why results were not received, corrective action to prevent recurrence, and the laboratory's self-evaluation of the results by comparing results to the all-participant statistics supplied by the PT Provider
42	No credit assigned due to absence of response or educational nature of challenge	Documentation that test is no longer performed in the laboratory or why result was not submitted.
44	This drug is not included in our test menu	Verify that drug is not tested on patient samples
77	Improper use of the exception code for this mailing	Documentation of the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade	Documentation of the investigation of the result as if it was an unacceptable result.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Melissa Kukiela BSRC, RRT Director, Respiratory Care Services</p> <p>2/3/2024</p> <hr/> <p>Date</p> <p>/s/</p> <hr/> <p>Lauren Stanoszek, MD Medical Director</p> <p>2/3/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i> Director, Respiratory Care Services</p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"><li>• <i>n/a</i></li></ul> <p>Initial effective date: 04/2012</p> <p>Review/Revision Date:</p> <p>04/11/2012 03/03/2014 03/01/2017 02/12/2019 09/21/2020 03/23/2023 02/03/2027</p> <p>Next review date: 02/3/2027</p>
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