Name of Policy: **Proficiency Test Protocol – Ungraded Exception Codes** **Policy Number**: 3364-107-315 **Approving Officer**: Medical Director, Clinical Pathology **Responsible Agent**: Director, Clinical Pathology Administrative Director, Lab **Scope**: Pathology Laboratory University of Toledo Medical Center	UTOLEDO HEALTH **Effective date:** 01/04/2025 **Original effective date**: 03/30/2005
Key words: College of American Pathologists (CAP), ungraded proficiency testing, testing review, exception codes, performance acceptability.	

☐	New policy proposal	☐	Minor/technical revision of existing policy
☐	Major revision of existing policy	☒	Reaffirmation of existing policy

(A) Policy statement

The College of American Pathologists (CAP) uses exception codes that signify that the PT for an analyte has not been graded. The laboratory must identify all of 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 Managers, Coordinators, Laboratory Supervisors, or Lead Technologists.

2. Medical Director will initial the individual findings/notations, review results, and sign entire report.

3. If an ungraded exception code is present, the all-participant statistics are reviewed for any explanation. Investigation of the following codes include, but are not limited to:

Code	Reason Code Description	Action Required
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.

Code	Reason Code Description	Action Required
20	No appropriate target/response; cannot be graded	Applies to a response that is not formally evaluated when a peer group is not established due to fewer than ten laboratories reporting. Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, all method, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (i.e., split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
21	Specimen problem	Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.
22	Result is outside the method/instrument reportable range.	Documentation of the comparison of results to the proper statistics supplied in the Participant Summary. Verify detection limits.
24	Incorrect response due to failure to provide a valid response code.	Document the laboratory's self-evaluation against the proper statistics and evaluation criteria supplied in the Participant Summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial	Documentation of the investigation of the result as if they were and unacceptable result and review the proper reference documents to gain knowledge of the reason your response is not appropriate.
26	Educational challenge	Review participant summary report for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. Response to CAP is not required.
27,31	Lack of participant or referee consensus	Document self-evaluation and compare results to the intended response when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (i.e., split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested.

Code	Reason Code Description	Action Required
28	Response qualified with a greater than or less than sign; or, unable to quantitate.	Applies to a response that is not formally evaluated when a less than or greater than sign is reported. Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the Participant Summary. Verify detection limits. Perform and document the corrective action of any unacceptable results.
30	Scientific Committee Decision	Applies to a response that is not penalized based on Scientific Committee Decision. Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary.
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 to the same level and extent for the period that commercial PT was not tested.
40/41	Results from kit not received and Results for this kit were received past the evaluation cut-off 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 Participant Summary. If PT specimens were not analyzed, perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested.
42	No credit assigned due to absence of response.	The Participant Summary indicates which tests are graded (see evaluation criteria) and which tests are not evaluated/educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result blank. The code 42 that appears on the evaluation is not a penalty. However, if a test is graded (regulated and nonregulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for all challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the kit instructions and/or the result form. Document corrective actions to prevent future failures.
44	This drug is not included in our test menu.	Verify that drug is not tested on patient samples and document to ensure proper future reporting.

Code	Reason Code Description	Action Required
45	Antimicrobial agent is likely ineffective for this organism or site of infection.	Document that laboratory performed a self-evaluation of written protocols and practices for routine reporting of antimicrobial susceptibility reports to patient medical records. Document that routine reporting of this result to clinicians for patient care is compliant with specific recommendations of relevant medical staff and committees (e.g. Infectious diseases, pharmacy and therapeutics, infection control) Response to CAP is not required.
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. Perform and document the corrective action if required.
35,43 88,92,46	Various Codes	No action required

Approved by: /s/ _____ Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology 1/10/2025 _____ Date *Review/Revision Completed by:* *Joshua Otiso, Administrative Director, Lab*	**Policies Superseded by This Policy:** • *Q-07b* Initial effective date: 03/30/2005 Review/Revision Date: 01/04/2025 Next review date: 01/04/2027