American Proficiency Institute

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December 18, 2025

Mr. William N. Parham, III
Director
Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
US Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
(Filed electronically)

RE: CLIA Proficiency Testing (CMS-10690; OMB 0938-1357)

Dear Mr. Parham:

Thank you for the opportunity to comment on the proposed collection of information regarding proficiency testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). On behalf of the American Proficiency Institute (API), these comments are specific to the reporting of microbiology proficiency testing (PT) results to proficiency testing programs.

Based in Traverse City, Michigan, API is one of the largest proficiency testing providers in the world, serving over 20,000 laboratories. Established in 1991, API offers innovative solutions and technical excellence for the proficiency testing needs of hospital and reference laboratories, physician offices, clinics, and point-of-care testing sites. Widely accepted, API earned ISO/IEC 17043 accreditation for operating proficiency testing schemes after an examination of its quality systems, statistical methods, reporting and interpretation.

We are concerned that the information collection, as written, is outside the scope of proficiency testing, and creates significant burdens to proficiency testing providers and the laboratories they serve.

Proficiency Testing Performance

The information collection rightly notes that an HHS-approved proficiency testing program "sends samples to a laboratory for analysis. After testing, the laboratory reports its results to the PT program. The program grades the results using the CLIA grading criteria and provides the laboratory with its

scores. PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel."

According to the Code of Federal Regulations, HHS approves a PT program that assesses the accuracy of a laboratory's response. Among the evaluation criteria, "a laboratory must identify the organisms to highest level that the laboratory reports results on patient specimens" and "a laboratory's performance will be evaluated on the basis of the average of its scores…"

In 2019, CMS issued a proposed rule, CLIA Proficiency Testing Regulations Related to Analytes and Acceptable Performance (CMS-3355-P), which proposed amending §§493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b) to state that laboratories must report proficiency testing results for microbiology organism identification to the highest level that they report results on patient specimens. While API supports efforts to encourage laboratories to report PT challenges in the same manner as patient specimens, issues were raised in comments to the proposed rule regarding the application of this effort. The final rule, issued on July 11, 2022, solicited public comment on Clarification for Reporting of Microbiology Organism Identification.

With the resulting December 1, 2025, information collection notice, we raise concerns regarding the following:

(1) Required analytes;
(2) Elements of successful PT participation;
(3) Definition of "highest" level of identification;
(4) Proficiency testing versus laboratory inspection

<u>Required Analytes Conflict</u>

It is unclear if the definition of required analytes under 42 CFR Part 493, Subpart I includes some of the "highest" level of microbiology organism identification currently reported on patient specimens. This particularly applies to identification beyond the species level. Laboratories, when enrolling in a proficiency testing program, may request their most specific or complex testing. Yet, there appears to be a conflict between what analytes are required under regulation versus what "highest level" reporting is required under the information collection.

The laboratory community needs guidance on whether the highest level reported on patients is intended to stop at the species level identifications, or include more specific tests. For example, there are tests that detect MRSA separately from *Staphylococcus aureus*; tests that detect certain genotypes of HPV in addition to the detection of the virus itself; tests that detect Herpes Simplex Virus Type 1 vs. Herpes Simplex Virus Type 2 (as opposed to Herpes Simplex Virus without a type). Additional examples include tests that identify a pathogen as Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), *E. coli* O157, or *Shigella*/Enteroinvasive *E. coli* (EIEC) as opposed to the *Shigella* genus or *E. coli* species.

Successful Participation in PT

The information collection notice states, "The information that the laboratory submits to the PT program will be used by the PT program to determine successful participation in PT." Successful participation in proficiency testing is determined by evaluation requirements set forth in regulation. For example, for bacteriology, section 493.911(c), *Evaluation of a laboratory's performance*, outlines how approved PT programs must assess the accuracy of a laboratory's response.

The regulation states, "A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example… evaluated on the basis of the average of its scores…" While *the laboratory* has an obligation to identify organisms as it performs them on patient specimens, *the PT program* is performing the evaluation based on a specific score.

The CMS State Operations Manual, Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (QSO-25-10-CLIA-revised) states for §493.821, "A laboratory must identify the organisms to highest level that the laboratory reports results on patient specimens. If a laboratory reports patient results to the genus level, that is the expectation for PT. Similarly, if a laboratory reports patient results to the species level, that would be the expectation for reporting PT results." The PT program does not use this information to determine successful participation in PT. It is instead an indication of what level the laboratory is reporting, and the PT program then evaluates that result.

Definition of "Highest Level" of Identification

Microbiology laboratories are responsible for enrolling annually in proficiency testing for their "highest" level of identification performed. It is neither usual or customary for laboratories to report this information specifically to PT programs, nor for PT programs to incorporate this information in its evaluation of test accuracy.

For each microbiology subspecialty, the annual PT program must include certain types of samples, such as, for bacteriology, "Gram stain including bacterial morphology; direct bacterial antigen detection; bacterial toxin detection; and detection and identification of bacteria which includes one of the following: detection of the presence or absence of bacteria without identification, or identification of bacteria; and antimicrobial susceptibility testing of select bacteria." This language is found at §493.911(b). The extent levels are not specified, nor are they specified for other microbiology subspecialties.

Laboratory practice varies considerably when it comes to reporting to "highest" level. For example, while full Gram stain and morphology may be reported on patients (e.g., Gram-positive cocci) most of the time, some laboratories may report "Gram positive organism" or "Organism present" depending on a patient's antibiotic use or history. In a different example, if laboratory instrumentation provided a 50/50 discrepant result between two organisms (same genus, different species), the laboratory may not be able to report full identification.

PT programs determine the target bacteria to be reported and its accuracy. PT programs do not report to the highest level; laboratories do. For PT programs to do so would create a significant burden of time and resources, and the benefit of such action – from a PT program – is unclear.

Proficiency Testing vs. Laboratory Inspection

As stated in the information collection, proficiency testing "independently verifies the accuracy and reliability of laboratory testing." PT does not oversee a laboratory's practice.

It is the role of accreditation programs, exempt states, and others charged with inspecting laboratories to determine if the laboratories they oversee are using the proper sample types, performing the appropriate test methods, and identifying microbiology organisms to the highest level. Accreditation surveyors and state inspectors are in a position to review a laboratory's documentation to determine if it is testing to the appropriate level.

PT programs cannot see into a laboratory to determine if a reported "highest" level reflects how it interacts with patients. An accreditation body can. PT programs do not use laboratory extent levels to determine successful participation in PT, but an accreditation body or inspector can determine if a laboratory is providing proper documentation to ensure regulations are met.

PT programs are responsible for designing programs so that any laboratory that reports, no matter the extent of testing, would have result options that fit how they would report for a patient. Further, reporting to species level for all five PT samples per event is not usual and customary for all laboratories. Laboratory inspectors would be able to check organism identification data points better during a laboratory's inspection, and ascertain if it aligns with patient testing. This information may be a checklist requirement for laboratory inspectors; it is not one for PT programs. The roles differ.

That said, PT programs should provide instruction to their enrolled laboratories that a laboratory must identify microbiology organisms to the highest level that the laboratory reports results on patient specimens.

We urge CMS to reconsider this proposed collection of information. This information collection as proposed is outside the scope of proficiency testing, and would add new and burdensome requirements to PT programs that may be more appropriate for accreditation bodies to conduct.

If you have questions or need additional details, please let me know.

Sincerely,

Sue Harmer
President