NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED PROFICIENCY TESTING STANDARDS

The Proposed Standards in the areas of Proficiency Testing were circulated for comment on October 11, 2024. The announcement was sent to NYS-permitted facilities that held or were in application for a permit. This distribution was by e-mail to the facility, the Director's e-mail address, and the laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended November 10, 2024. Four (4) comments were received.

The standards are considered to be accepted and will be adopted and effective as of December 6, 2024.

Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation No change to existing standard	Please see 42 CFR §493.801 for federal Proficiency Testing regulations. Information on Department notification and annual Proficiency Testing enrollment is available in the PT Guide and on our website and available at: https://www.wadsworth.org/regulatory/clep/pt. Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available. When laboratories use more than one method to determine results for a given analyte, only the primary method should be evaluated using proficiency testing. Secondary methods must be assessed against the primary method as outlined in Test Performance Specification Standard of Practice 5.

Comment 1:
If we have the Hologic Aptima (Primary), Biofire (secondary) and Cepheid (secondary) for Covid/flu/RSV testing. Should the proficiency be tested on the Panther only for Covid/Flu or on the Biofire? We currently run the proficiency on the Biofire Respiratory Panel. When the Panther is down, Cepheid, which is our back up instrument becomes our primary instrument and when both Panther and Cepheid are down the Biofire becomes our Primary instrument, until the Panther/Cepheid is back up and operational. This is where my dilemma lies. The Biofire reports out more analytes than the Cepheid(Covid/Flu/RSV) or the Panther Aptima(Covid/FLU only). I get conflicting answers so would like some clarity on this with the new proposed standards. Is it ok to continue to run the proficiency on the Biofire (CAP-IDR)?

Response 1:
According to the Centers for Medicare and Medicaid Services (CMS), the laboratory should perform proficiency testing using the method that is considered primary *at the time of the proficiency testing event.* For example, and based on the description above, if the Hologic instrument is down when the proficiency samples arrive, then the

Cepheid should be used (indicated as first backup). If the Hologic and Cepheid are both down when the proficiency samples arrive, then the BioFire should be used (indicated as second backup).

Comment 2 :
Please clarify if there is a specific timeframe for performing PT for the secondary method? Should facilities wait until PT for the primary method has been submitted and results have been received? Can PT for the secondary method be used for method comparison?

Response 2:
There is no requirement for performing proficiency testing for secondary methods. Secondary methods must be assessed against the primary method as outlined in Test Performance Specification Standard of Practice 5 (TP S5): Comparability of Test Results.

Comparisons must be performed semi-annually (i.e., an event that takes place two times during the year, with the first event taking place in the first six months of the year and the second event in the last six months of the year, and where the interval between events is at least four months and not more than eight months) at a minimum.

If the proficiency test (PT) specimens performed for the primary method are used to assess the secondary method against the primary method; the facility must wait until after the close of the PT event (the date and hour result submissions will no longer be excepted by the PT provider) to perform the assessment.

Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis

Unless instructed otherwise by the proficiency testing provider, laboratories must use the same test process for proficiency testing samples that is used for patient specimens.

Proficiency testing samples must be:

a) incorporated into the laboratory's routine workflow;

b) rotated among all operators that perform testing;

c) in microbiology, reported to the highest level of organism identification performed by the laboratory.

Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)

Comment 1:
This wording is problematic because even in laboratories that speciate microorganisms, not all organisms can be speciated using routine methods. For example, laboratories that perform Giemsa-stained peripheral blood smears can identify *Plasmodium* species (P. *Falciparum, P. Vivax*, etc), but organisms in the genus *Babesia* are always reported as *Babesia* spp. This is consistent with the guidance provided in the ASM Manual of Clinical Microbiology, 13th edition, p. 2771, "It is not possible to differentiate the various human *Babesia* species by morphology; this requires molecular methods." It is also the format that the Wadsworth Parasitology lab uses when reporting the results of Giemsa-stained smear interpretations.

We propose that "Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis" part c be clarified as follows: "c) in microbiology, reported to the highest level of organism identification (for the relevant organism) performed for by the laboratory.

Response 1:

Added to Guidance: The highest level of organism identification means the highest level of identification performed and resulted by the laboratory for patient specimens for the organism identified.

Proficiency Testing Standard of Practice 16 (PT S16): Proficiency Testing Documentation

Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples:

a) steps taken in handling, preparing, processing, examining, testing and reporting all results in the proficiency test event;
b) the proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements; and
c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to Document and Specimen Retention Standard of Practice 11.

Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)

Comment 1:

What specifically do you mean with regard to handling? Is it the collection of the sample or the receipt of a collected sample? What is the difference between handling and preparing? What if you receive frozen samples from a 3rd party? Can you refer to a SOP that addresses sample handling in the Proficiency Testing Documentation?

Response 1:

According to CMS, specimen handling is the process of collecting, preserving, and transporting specimens so that they are stable enough to provide accurate results for clinical interpretation. CMS defines specimen preparation as the process of preparing a specimen for analysis in-house or for sending to a reference laboratory. This may include receiving the specimen, accessioning the specimen, preparing slides, and inoculating primary culture media. External proficiency test providers typically include instructions for the handling and preparation of their proficiency specimens.

In general, for specimens received frozen from a third-party, documentation of specimen handling and preparation would begin at receipt of the specimen. Proficiency specimens received from a third-party must be handled per the requirements in **Proficiency Testing Standard of Practice 8 (PT S8): Proficiency Testing Referral Notification.**

The laboratory may refer to a sample handling procedure if relevant supporting documentation is maintained. (i.e. temperature records, proficiency test provider's instructions for specimen handling, etc.)