Proficiency Testing Recommendations

1. **Analyte Inclusion/Prioritization and Grading Criteria**
    a. There should be a defined list of analytes for which PT is required. If legally possible, those analytes should be separate from, but linked to, regulations, allowing the list to be more flexible.
    b. Inclusion Criteria for determining required PT analytes should be scientifically based.
    c. Factors to be considered for adding required PT analytes to subpart I of the CLIA regulations should include:
        i. Whether PT exists and material is available
        ii. The volume of testing for an analyte
        iii. Clinical relevance
        iv. Cost of adding an analyte
    d. Criteria used to assess clinical relevance of an analyte should include consideration of:
        i. Testing when a treatment decision is made solely on the result of that test.
        ii. Tests that have critical values associated, i.e. results that require immediate communication with clinicians due to their life-threatening nature or serious risk to the patient.
        iii. National practice guidelines that include testing the analyte
    e. There should be a two-year phase in period for implementation of required PT after adding analytes to the list.
    f. The required number of PT challenges and frequency (five challenges, three times per year) should not be changed.
    g. Ideally every analyte should be assessed with traditional PT. If PT is not available, however, laboratories should continue to use alternative proficiency assessment as now required by CLIA.

Criteria for Acceptable Performance

2. Grading criteria should be periodically reviewed for all analytes that require PT for continued clinical relevance or when other relevant information becomes available.

3. Information gathered during the phase-in process for newly required PT should be used to scientifically establish grading criteria.

4. An indeterminate category should be considered an acceptable answer for certain analytes when applicable.

5. Peer grouping should be retained when appropriate as a component of the grading criteria.

6. Definition of the term “Peer Group” for possible inclusion in the regulations: A group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems.

7. All vendors involved in the production of PT material need to work to minimize matrix effects.

8. Designations for PT samples being ungradable (reason codes) should be clarified to distinguish between situations when there are too few participants to grade and sufficient number of participants but consensus is not reached.

Microbiology PT

9. A system for categorizing levels of service must be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing.
   Laboratories need to declare their patient reporting practices for organisms included in each PT challenge. However, PT programs may only gather this information as it is the inspecting agency’s responsibility to review and take action if necessary.

10. The regulations need to include for all microbiology subspecialties, as applicable, stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification or detection.

11. Require PT for a generic list of organisms in each subspecialty. For example, in bacteriology the groups listed should include gram-negative bacilli, gram-positive bacilli, gram-negative cocci, and gram-positive cocci.

12. For PT, patient histories and source should be provided, however this information should not preclude the laboratory from performing PT.

13. PT results for Gram stains should include both stain reaction and morphology.

14. Lower the mixed culture requirement from 50% to 25% for PT challenges of both sample types (those that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present).

15. Required PT for antimicrobial susceptibility and/or resistance testing should be increased to two challenges per event for a total of six challenges per year in bacteriology and should include one gram-positive and one gram-negative organism in each event.

16. PT should be required for laboratories that perform susceptibility and/or resistance testing in all microbiology subspecialties. It should include two challenges per event for a total of six challenges per year and should include resistant organisms.

17. PT for direct antigen testing should be required for all subspecialties.

18. Retain the five required challenges per event and 80% required consensus for grading.

19. All PT programs should be required to provide CMS with the overall score for each subspecialty, with a line item underneath that includes a score on the individual PT tests or procedures that comprised the subspecialty score - such as stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification and detection.

PT Referral

20. Distinguish acceptable "PT referral" from unacceptable PT referral with the "intent to defraud" in regulations at §493.801(b)(4) allowing CMS more flexibility in imposing sanctions on laboratories.

21. Designation of acceptable PT referral would allow laboratories to treat PT exactly as patient samples and perform reflex or referral testing when it is included in their standard procedure for patients.

22. Laboratories should provide documentation to the referral laboratory on the nature of the referral. Referral laboratories should not be penalized.