

**April 2024**

**CHANGES AHEAD FOR THE 2025 PROGRAM YEAR**

We want to inform you of significant and important changes to the [CLIA Proficiency Testing Regulations Related to Analytes and Acceptable Performance](#). This is the first time since 1992 that these regulations have changed. The Proficiency Testing Final Rule (CMS-3355-F), while effective [July 11, 2024, will be implemented on January 1, 2025](#). Meaning these changes may affect your 2025 enrollment and grading.

The final rule includes [the addition and deletion of regulated analytes](#) and updates the criteria for acceptable performance. 29 analytes added to the regulated analytes list will require programs with 5 samples per testing event. 6 analytes have been removed from the regulated analyte list. For Bacteriology, the gram stain morphology will become graded, and 2 susceptibility challenges will be required per event. [To meet the new requirements, several AAB-MLE modules will be reconfigured from 2 samples to 5 samples. Price increases are expected.](#)

Acceptable ranges will be tightened for many analytes. [AAB-MLE is already using the new criteria for grading most of the currently non-regulated analytes.](#) We cannot begin using the new criteria to grade currently regulated analytes until 2025. **To determine the impact the grading changes will have on your laboratory's currently regulated analyte performance, it may be helpful for you to evaluate the performance of your 2024 results by applying the new 2025 criteria.** Refer to the AAB-MLE [Program Guide](#) "Analyte Index With Grading Ranges". Currently regulated analytes are indicated with 'CMS' in the first column of the table.

[AAB-MLE will help your lab meet the new PT requirements by adjusting your 2025 renewal order as needed to ensure you have the required number of challenges for regulated analytes. These enrollment changes will be reflected on your 2025 Order Verification to be sent out in the fall of 2024.](#)

**As always feel free to reach out to us so we can offer any needed assistance. You can always reach us by calling at 800-234-5315 or e-mailing at [mle@aab-mle.org](mailto:mle@aab-mle.org).**