

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Quality Safety & Oversight Group

March 15, 2023

Dear PT Program Providers,

The final rule [CMS-3355-F](#), Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance, was published in the Federal Register on July 11, 2022. This final rule will affect laboratories that perform testing for any of the analytes or microbiology subspecialties listed in the CLIA regulations under subpart I. It will also affect any laboratory that participates in PT referral involving waived testing.

This final rule includes:

- the addition and deletion of analytes or tests that require proficiency testing (PT), as well as updates the criteria for acceptable performance and administrative processes for CLIA PT programs.
- an update to align the CLIA regulations with the statute (42 U.S.C. 263a (i)(4)), which does not exclude waived tests from the ban on improper PT referral.

The revisions to PT requirements related to the addition and deletion of analytes or microbiology tests and updates to the criteria for acceptable performance and administrative processes for PT programs (§§ 493.2 and 493.801 through 493.959) are effective on July 11, 2024, two years after the publication date of the final rule in the Federal Register. **The implementation date for the laboratories and PT program providers for these revisions will be January 01, 2025 which is in alignment with our current process for PT program providers and PT enrollment.**

Learn more about the final rule in the [Federal Register](#).

If you have any questions, please contact Sarah Bennett and Penny Keller at the following email address:

Sarah.Bennett1@cms.hhs.gov and Penny.Keller@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Brandush", is positioned above the typed name.

Gregg S. Brandush, RN, JD
Director, Division of Clinical Laboratory Improvement
and Quality
Quality Safety and Oversight Group
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Proficiency Testing Changes for 2025

On July 11, 2022, the Centers for Medicare & Medicaid Services (CMS) published final rule CMS-3355-F. This rule added new regulated analytes to CLIA, revised grading criteria for some current analytes, and made other small changes affecting PT enrollment and grading.

The following tables summarize the changes that will go into effect January 1, 2025. API already offers 5-sample programs for most new analytes, and the associated catalog numbers are shown. If you would like to adjust your proficiency testing enrollments for the 2024 calendar year, please contact us at (800) 333-0958.

Beginning January 1, 2025, labs performing non-waived testing for the analytes below **must** be enrolled in a 5-sample program except in microbiology, where programs can be combined to meet the 5-sample requirement for each subspecialty.

Note that API will use the same grading criteria for all methods and all programs containing these analytes. In addition, some 2-sample programs may be discontinued in 2025 due to anticipated lack of enrollment. 2025 renewal forms will reflect program changes, and more information will be provided at that time.

Miscellaneous Changes

| HEMATOLOGY |
|--|
| Participants will be required to enroll in proficiency testing for both manual and automated blood cell differentials. Scores for both will be submitted to CMS. |
| GENERAL IMMUNOLOGY |
| Qualitative Anti-HBs and Anti-HCV will be considered regulated. The grading criteria is 80% consensus for the targeted result (positive/reactive or negative/nonreactive). |
| IMMUNOHEMATOLOGY |
| Antibody Screen (Unexpected Antibody Detection) will no longer use 80% for a passing score. Like most other immunochemistry analytes, a score of 100% (all 5 samples acceptable) will need to be obtained in order to pass a test event. |

New CMS Regulated Analytes and Grading Criteria

| ROUTINE CHEMISTRY | | | |
|---------------------------------------|-------------------------|-------------------------------|------------------------------|
| Analyte | 5-Sample Catalog # | Current API Criteria | New CMS Criteria |
| BNP | 140 | ± 10 pg/mL or 3 SD (greater) | ± 30% |
| NT pro-BNP | 140 | ± 10 pg/mL or 2 SD (greater) | ± 30% |
| Cholesterol, LDL (measured) | 121, 122 | ± 2 SD | ± 20% |
| CO2 | 121, 122 | ± 3 SD | ± 20% |
| tCO2 | 112, 145 | ± 3 SD | ± 20% |
| Ferritin | 180 | ± 3 SD | ± 20% |
| GGT | 122 | ± 20% | ± 5 U/L or 15% (greater) |
| Glycated Hemoglobin (HbA1c) | 126, 195 | ± 3 SD or 20% | ± 8% |
| Phosphorus | 122 | ± 2 SD | ± 0.3 mg/dL or 10% (greater) |
| PSA | 180, 183 | ± 0.4 ng/mL or 3 SD (greater) | ± 0.2 ng/mL or 20% (greater) |
| TIBC (measured) | 122 | ± 2 SD | ± 20% |
| Troponin I | 140 | ± 0.3 ng/mL or 3 SD (greater) | ± 0.9 ng/mL or 30% (greater) |
| Troponin T | 140 | ± 0.1 ng/mL or 2 SD (greater) | ± 0.2 ng/mL or 30% (greater) |
| ENDOCRINOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current API Criteria | New CMS Criteria |
| CA 125 | 183 | ± 2 SD | ± 20% |
| CEA | 180, 183 | ± 3 SD | ± 1 ng/mL or 15% (greater) |
| Estradiol | 180 | ± 2 SD | ± 30% |
| Folate | 180 | ± 1 ng/mL or 3 SD (greater) | ± 1 ng/mL or 30% (greater) |
| FSH | 180 | ± 3 SD | ± 2 IU/L or 18% (greater) |
| Luteinizing Hormone | 180 | ± 3 SD | ± 20% |
| Parathyroid Hormone | 182 | ± 2 SD | ± 30% |
| Progesterone | 180 | ± 3 SD | ± 25% |
| Prolactin | 180 | ± 3 SD | ± 20% |
| Testosterone | 180 | ± 3 SD | ± 0.2 ng/mL or 30% (greater) |
| Vitamin B-12 | 180 | ± 3 SD | ± 30 pg/mL or 25% (greater) |
| TOXICOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current API Criteria | New CMS Criteria |
| Acetaminophen | 132, 136 | ± 2.5 µg/mL or 3 SD (greater) | ± 3 µg/mL or 15% (greater) |
| Salicylates | 132, 136 | ± 2.8 mg/dL or 3 SD (greater) | ± 0.2 mg/dL or 15% (greater) |
| Vancomycin | 132, 136 | ± 2 µg/mL or 20% (greater) | ± 2 µg/mL or 15% (greater) |
| HEMATOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current API Criteria | New CMS Criteria |
| INR | 214, 216, 217, 249, 250 | ± 3 SD | ± 15% |
| GENERAL IMMUNOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current API Criteria | New CMS Criteria |
| C-reactive protein (high-sensitivity) | 443 | ± 0.2 mg/dL or 2 SD (greater) | ± 0.1 mg/dL or 30% (greater) |

Revised Grading Criteria for Current Regulated Analytes

| ROUTINE CHEMISTRY | | | |
|-----------------------|--------------------|-------------------------------|-------------------------------|
| Analyte | 5-Sample Catalog # | Current CMS Criteria | New CMS Criteria |
| Albumin | 122 | ± 10% | ± 8% |
| Alkaline phosphatase | 122 | ± 30% | ± 20% |
| ALT / SGPT | 121, 122 | ± 20% | ± 6 U/L or 15% (greater) |
| Amylase | 122 | ± 30% | ± 20% |
| AST / SGOT | 121, 122 | ± 20% | ± 6 U/L or 15% (greater) |
| Cholesterol, HDL | 121, 122 | ± 30% | ± 6 mg/dL or 20% (greater) |
| Creatine Kinase / CK | 122, 140 | ± 30% | ± 20% |
| CK-MB | 140 | ± 3 ng/mL or 3 SD (greater) | ± 3 ng/mL or 25% (greater) |
| Creatinine | 112, 121, 122, 145 | ± 0.3 mg/dL or 15% (greater) | ± 0.2 mg/dL or 10% (greater) |
| Glucose | 112, 121, 122, 145 | ± 6 mg/dL or 10% (greater) | ± 6 mg/dL or 8% (greater) |
| Iron | 122 | ± 20% | ± 15% |
| LD / LDH | 122 | ± 20% | ± 15% |
| Magnesium | 122 | ± 25% | ± 15% |
| pO ₂ | 111, 112, 145 | ± 3 SD | ± 15 mmHg or 15% (greater) |
| Potassium | 112, 121, 122, 145 | ± 0.5 mmol/L | ± 0.3 mmol/L |
| Total Protein | 122 | ± 10% | ± 8% |
| Triglycerides | 121, 122 | ± 25% | ± 15% |
| Uric Acid | 121, 122 | ± 17% | ± 10% |
| ENDOCRINOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current CMS Criteria | New CMS Criteria |
| Cortisol | 122, 125 | ± 25% | ± 20% |
| Free Thyroxine (FT4) | 122, 125, 175 | ± 3 SD | ± 0.3 ng/dL or 15% (greater) |
| HCG (serum-quant) | 409 | ± 10 mIU/mL or 3 SD (greater) | ± 3 mIU/mL or 18% (greater) |
| T-Uptake | 122, 125, 175 | ± 3 SD | ± 18% |
| Triiodothyronine (T3) | 122, 125, 175 | ± 3 SD | ± 30% |
| TSH | 122, 125, 175 | ± 3 SD | ± 0.2 mIU/L or 20% (greater) |
| TOXICOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current CMS Criteria | New CMS Criteria |
| Alcohol | 137 | ± 10 mg/dL or 25% (greater) | ± 20% |
| Blood Lead | 172 | ± 4 µg/dL or 10% (greater) | ± 2 µg/dL or 10% (greater) |
| Carbamazepine | 132, 136 | ± 25% | ± 1 µg/mL or 20% (greater) |
| Digoxin | 132, 136 | ± 0.2 ng/mL or 20% (greater) | ± 0.2 ng/mL or 15% (greater) |
| Lithium | 132, 136 | ± 0.3 mmol/L or 20% (greater) | ± 0.3 mmol/L or 15% (greater) |
| Phenobarbital | 132, 136 | ± 20% | ± 2 µg/mL or 15% (greater) |
| Phenytoin | 132, 136 | ± 25% | ± 2 µg/mL or 15% (greater) |
| Theophylline | 132, 136 | ± 25% | ± 20% |
| Tobramycin | 132, 136 | ± 25% | ± 20% |
| Valproic Acid | 132, 136 | ± 25% | ± 20% |
| HEMATOLOGY | | | |
| Analyte | 5-Sample Catalog # | Current CMS Criteria | New CMS Criteria |
| Hematocrit | See catalog | ± 6% | ± 4% |
| Hemoglobin | | ± 7% | ± 4% |
| Red Cell Count | | ± 6% | ± 4% |
| White Cell Count | | ± 15% | ± 10% |

| GENERAL IMMUNOLOGY | | | |
|---------------------|--------------------|----------------------|----------------------------|
| Analyte | 5-Sample Catalog # | Current CMS Criteria | New CMS Criteria |
| Alpha-1-Antitrypsin | 436 | ± 3 SD | ± 20% |
| Alpha-fetoprotein | 122 | ± 3 SD | ± 20% |
| Complement C3 | 436 | ± 3 SD | ± 15% |
| Complement C4 | 436 | ± 3 SD | ± 5 mg/dL or 20% (greater) |
| IgA | 436 | ± 3 SD | ± 20% |
| IgE | 419, 436 | ± 3 SD | ± 20% |
| IgG | 436 | ± 25% | ± 20% |
| IgM | 436 | ± 3 SD | ± 20% |

Microbiology Changes for 2025

CLIA requires laboratories performing microbiology tests that are regulated for proficiency testing to test five regulated challenges per test event in each sub-specialty. The five sub-specialties are Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology. The following are new additions to the CLIA Microbiology requirements and will be scored for CMS beginning January 1, 2025.

We have already made changes to Microbiology programs for 2024. We will communicate further as the implementation date of January 1, 2025 draws closer. If you have any questions about the new requirements, please contact our Technical Support department at (800) 333-0958 or at TechSupport@api-pt.com.

| BACTERIOLOGY | |
|--|--|
| CLIA Category | API Analyte |
| Gram stain morphology | Gram stain morphology (#320, #328) |
| Bacterial toxin detection | <i>C. difficile</i> toxin (#347, #350) Shiga toxin (#343) Identification of bacterial toxins (#369 – GI Panel) |
| Antimicrobial susceptibility | Two samples required per event (#314, #321, #328, #924) |
| MYCOBACTERIOLOGY | |
| CLIA Category | API Analyte |
| Detection of presence/absence of mycobacteria, without identification | <i>M. tuberculosis</i> detection (molecular) (#372) |
| MYCOLOGY | |
| CLIA Category | API Analyte |
| Direct fungal antigen detection | Cryptococcal antigen (#345) |
| Detection of presence/absence of fungi and aerobic actinomycetes, without identification | <i>Candida</i> sp. (#324 – Affirm VP) |
| Identification of fungi and aerobic actinomycetes | Molecular identification of yeasts (#371 – Meningitis Panel, #376 – Vaginal Panel, #389 – UTI Panel, #390 – Joint/Wound Infection Panel) Molecular identification of fungi (#391 – Nail Fungus Panel) <i>Candida auris</i> (#393 – new for 2024) |
| PARASITOLOGY | |
| CLIA Category | API Analyte |
| Direct parasite antigen detection | Rapid malaria detection (#382) |
| Identification of parasites | Molecular identification of parasites (#369 – GI Panel, #376 – Vaginal Panel, #392 – STI Panel) <i>Trichomonas vaginalis</i> (#324, #362) |
| VIROLOGY – NO CHANGES | |