

TECHNICAL SERVICE BULLETIN

2024-029



Date Issued: January 1, 2025

Subject: Clinical Laboratory Improvement Amendments (CLIA 2024) and MSDRx Infinity

Explanation:

Testing technology has undoubtedly advanced since 1992, when the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) was introduced. Some of today's routine tests were not even required then. These factors led the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to undertake an extensive review process that resulted in amended CLIA proficiency testing (PT) regulations for the first time in 32 years.

The final rule, announced in 2022, became effective earlier this year. Its implementation date for newly-regulated analytes and updated PT acceptance limits (ALs) is January 1, 2025. CMS and the CDC delayed implementation of these parts of the regulation to align with the calendar year enrollment requirements for laboratories and the annual approval process for PT providers.

Changes include, 29 newly regulated analytes and tighter proficiency testing acceptable limits for many currently regulated analytes, along with changes to grading and reporting.

LGC will be adopting CLIA 2024 Criteria for Acceptable Performance (Acceptance limits) within their informatics solutions MSDRx Infinity starting January 1, 2025.

Please contact LGC Maine Standards Technical Support if you have any questions at 1-800-377-9684.

Contact Information: Technical Support Department
LGC Clinical Diagnostics, Inc.
221 US Route 1
Cumberland Foreside, ME 04110
Phone: 1-800-377-9684
+1-207-892-1300
Fax: +1-207-892-2266
E-mail: msc.techsupport@LGCGroup.com