

Clinical Laboratory Improvement Amendments of 1988 (CLIA); Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes

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Clinical Laboratory Improvement Amendments of 1988 (CLIA); Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes

This proposed rule would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow for virtual access under the CLIA certificate of the primary testing laboratory that generated the data, with the exception of the subspecialty of cytology, and the use of digital images for gynecologic cytology proficiency testing. This proposed rule also includes proposed changes to personnel qualification requirements and other proposed changes pertaining to SARS-CoV-2 reporting requirements, certificate requirements, test reporting requirements, enforcement requirements, public consultation requirements, and editorial and technical updates. These proposed updates aim to strengthen the Federal oversight of clinical laboratories and ensure accurate and reliable patient test results while adapting to modern technological capabilities and industry needs, including workforce shortages.

Agency: Health and Human Services Department, Centers for Medicare & Medicaid Services.

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