

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0708034	(X3) Date Survey Completed 08/13/2025
Name of Provider or Supplier Lab Clinico Plaza Centro	Street Address, City, State #233 Rafael Cordero Ave, Caguas, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Plaza Centro on August 13, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on August 13, 2025.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2024-2025) and laboratory director interview on August 13, 2025 at 11:56 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials (normal and abnormal controls), when the laboratory processed and reported 1250 patient urinalysis samples from July 1, 2024 to August 13, 2025. The findings include: 1. The laboratory performs urinalysis tests with the Mission U120 Ultra Urine Analyzer. 2. The urinalysis quality control records reviewed (years 2024-2025) on August 13, 2025 at 11:46 AM, from July 1, 2024 to August 13, 2025, showed that there was no evaluation of the manufacturer's stated values for the normal control material lot number UB1526011A, and abnormal control material lot number UB1526012A, prior</p>

to placing them in routine use on July 1, 2024. 3. The laboratory director confirmed on August 13, 2025 at 11:56 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests prior to placing them in routine use, performed by the Mission U120 Ultra Urine Analyzer, when they processed and reported 1250 patient samples from July 1, 2024 to August 13, 2025.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on Mycoplasma Pneumoniae IgM test quality control records review (years 2024-2025), manufacturer's instructions review, Individualized Quality Control Plan (IQCP) review, and laboratory director interview on August 13, 2025 at 12:30 PM; it was determined that the laboratory did not document the procedural control for negative and positive controls, when 81 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test from January 8, 2025 to August 13, 2025. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. On August 13, 2025 at 12:15 PM, the IQCP for Mycoplasma pneumoniae IgM tests was reviewed, and it was approved and signed by the laboratory director on January 2, 2025, and it establishes to record and evaluate Quality Control (QC) results according to QC acceptability criteria, and document the procedural control with any specimen or control reagent. 3. On August 13, 2025 at 12:20 PM the manufacturer's instructions were reviewed, and it establishes to document the procedural control with any specimen or control reagent, to test the individual specimen for proper flow and reagent performance. 4. On August 13, 2025 at 12:22 PM; the quality control records (years 2024-2025) of Mycoplasma Pneumoniae IgM test were reviewed, and showed that the laboratory did not document the procedural control for negative and positive controls from January 8, 2025 to August 13, 2025. 5. The laboratory director confirmed on August 13, 2025 at 12:30 PM, that the laboratory did not document the procedural control for negative and positive controls, when 81 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test from January 8, 2025 to August 13, 2025.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on urinalysis and Mycoplasma Pneumoniae IgM quality control records, manufacturer's instructions, and interview with the laboratory director on August 13, 2025 at 12:30 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5469 and D5481.

D6148

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463(a)(4)

(a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

This STANDARD is not met as evidenced by:

Based on Mycoplasma Pneumoniae IgM test quality control records review (years 2024-2025), manufacturer's instructions review, Individualized Quality Control Plan (IQCP) review, urinalysis quality control records, and interview with the laboratory director, and general supervisor (also testing personnel), it was determined that the laboratory general supervisor failed to monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained for Mycoplasma Pneumoniae IgM and urinalysis tests. Refer to D5469 and D5481.