

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1060233	(X3) Date Survey Completed 03/28/2025
Name of Provider or Supplier Laboratorio Clinico Freytes	Street Address, City, State Calle 1 B 1-9 Villas De Loiza, Loiza, 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 Freytes on March 28, 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 March 28, 2025.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing scores (year 2024), CASPER Report 0155D scores, proficiency laboratory records and interview with the laboratory director on March 28, 2025 at 9:20 AM, it was determined that the laboratory failed to take corrective action when obtained an unsatisfactory score in the total protein analyte in the third proficiency testing event of the year 2024. The finding includes: 1. The Puerto Rico Proficiency and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: Total Protein a. Third testing event year 2024 - 60% 2. The laboratory proficiency records was reviewed on March 28, 2025 at 9:08 AM, and showed that the laboratory failed to take corrective action when obtained an unsatisfactory score in the total protein analyte in the third proficiency testing event of the year 2024. 3. The laboratory director confirmed on March 28, 2025 at 9:20 AM, that the laboratory failed to take corrective action when</p>

obtained an unsatisfactory score in the total protein analyte in the third proficiency testing event of the year 2024.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on Mycoplasma Pneumoniae IgM test quality control records review, manufacturer's instructions review, and laboratory director interview on March 28, 2025 at 10:53 AM, it was determined that the laboratory failed to monitor and document the room temperature, when 81 out of 81 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test from January 8, 2025 to March 25, 2025. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. On March 28, 2025 at 10:45 AM the manufacturer's instructions were reviewed, and it establishes to perform the test procedures at room temperature from 22 to 25 C. 3. On March 28, 2025 at 10:50 AM, review of the Mycoplasma pneumoniae IgM quality control records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma pneumoniae IgM from January 8, 2025 to March 25, 2025. 4. The laboratory director confirmed on March 28, 2025 at 10:53 AM, that the laboratory did not monitor nor document the room temperature when they processed the patient's specimens for Mycoplasma pneumoniae IgM test. The laboratory processed and reported 81 out of 81 patient samples for Mycoplasma pneumoniae IgM test from January 8, 2025 to March 25, 2025.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on the Human Chorionic Gonadotropin (hCG) quality control records review, manufacturer's instructions and laboratory director interview on March 28, 2025 at 11:29 A.M., it was determined that the laboratory did not perform the external negative control material each day of patient testing. The laboratory processed and reported 15 patients sample from January 2025 to March 2025. The findings include: 1. The manufacturer's instructions were reviewed on March 28, 2025 at 11:10 A.M. The manufacturer established that the external positive and negative control must be performed every day of patient testing. 2. Review of the hCG quality control records on March 28, 2025 at 11:15 A.M., showed that the laboratory did not perform the external negative control material each day of patient testing. The laboratory processed and reported 15 patients sample from January 2025 to March 2025. 3. The

	<p>laboratory director confirmed on March 28, 2025 at 11:29 A.M., that the laboratory failed to perform the negative external control material each day of patient testing. The laboratory processed and reported 15 patients sample from January 2025 to March 2025.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing scores (year 2024), CASPER Report 0155D scores, proficiency laboratory records and interview with the laboratory director (sole personnel) on March 28, 2025 at 9:20 AM, it was determined that the laboratory director failed to take corrective action when obtained an unsatisfactory score in the total protein analyte in the third proficiency testing event of the year 2024. Refer to D2094.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control records and interview with the laboratory director on March 28, 2025 at 11:48 A.M.; it was determined that the laboratory director (sole personnel) did not ensure that the quality control were follow. D5413, D5449.</p>