

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0690738	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Lab Clin Referencia Cima	Street Address, City, State Calle Saturnino Rodriguez #7, Yabucoa, 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 the Laboratorio Clinico Referencia CIMA on December 17, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on December 17, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 Condition: Bacteriology 42 CFR 493.1441 Condition: Laboratory Director
D2025	<p>BACTERIOLOGY CFR(s): 493.823(c)</p> <p>(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, Proficiency Testing Service Program 2024 Schedule, and laboratory general supervisor interview on December 17, 2025, at 10:00 A.M., it was determined that the laboratory failed to report to the PRPTSP, the bacteriology proficiency testing results within the timeframe established by the proficiency testing program. The laboratory processed and reported 1,998 out of 1,998 bacteriology patient tests from September 2024 to April 2025. The findings include: 1. The PRPTSP and CASPER report were reviewed on December 17, 2025, at 10:00 A.M., from February 2024 to December 2025. 2. The Proficiency Testing Service Program 2024 schedule showed that the deadline for submission of results for the third testing event for Microbiology was December 20, 2024. 3. The laboratory obtained a score of 0% for the third testing event for gram stain, bacteriology identification and bacteriology antimicrobial susceptibility. 4. During interview on December 17, 2025, at 10:15 A.M., the laboratory general supervisor confirmed that the laboratory failed to report bacteriology proficiency testing results for the third</p>

testing event within the timeframe established by the PRPTSP. 5. The laboratory processed and reported 1,998 out of 1,998 bacteriology patient tests from September 2024 to April 2025.

D2052

PARASITOLOGY
CFR(s): 493.829(c)

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:
Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, Proficiency Testing Service Program 2024 Schedule, and laboratory general supervisor interview on December 17, 2025, at 10:00 A.M., it was determined that the laboratory failed to report to the PRPTSP, the parasitology proficiency testing results within the timeframe established by the proficiency testing program. The laboratory processed and reported 106 out of 106 parasitology patient tests from September 2024 to April 2025. The findings include: 1. The PRPTSP and CASPER report were reviewed on December 17, 2025, at 10:00 A.M., from February 2024 to December 2025. 2. The Proficiency Testing Service Program 2024 schedule showed that the deadline for submission of results for the third testing event for Microbiology was December 20, 2024. 3. The laboratory obtained a score of 0% for the third testing event for identification of parasitology. 4. During interview on December 17, 2025, at 10:15 A.M., the laboratory general supervisor confirmed that the laboratory failed to report parasitology proficiency testing results for the third testing event within the timeframe established by the PRPTSP. 5. The laboratory processed and reported 106 out of 106 parasitology patient tests from September 2024 to April 2025.

D2071

SYPHILIS SEROLOGY
CFR(s): 493.835(c)

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:
Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, Proficiency Testing Service Program 2024 Schedule, and laboratory general supervisor interview on December 17, 2025, at 10:00 A.M., it was determined that the laboratory failed to report to the PRPTSP, the syphilis serology proficiency testing results within the timeframe established by the proficiency testing program. The laboratory processed and reported 1,004 out of 1,004 syphilis serology patient tests from September 2024 to April 2025. The findings include: 1. The PRPTSP and CASPER report were reviewed on December 17, 2025, at 10:00 A.M., from February 2024 to December 2025. 2. The Proficiency Testing Service Program 2024 schedule showed that the deadline for submission of results for the third testing event for Diagnostic Immunology was December 20, 2024. 3. The laboratory obtained a score of 0% for the third testing event for syphilis serology. 4. During interview on December 17, 2025, at 10:15 A.

	<p>M., the laboratory general supervisor confirmed that the laboratory failed to report syphilis serology proficiency testing results for the third testing event within the timeframe established by the PRPTSP. 5. The laboratory processed and reported 1,004 out of 1,004 syphilis serology patient tests from September 2024 to April 2025.</p>
<p>D2081</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, Proficiency Testing Service Program 2024 Schedule, and laboratory general supervisor interview on December 17, 2025, at 10:00 A.M., it was determined that the laboratory failed to report to the PRPTSP, the general immunology proficiency testing results within the timeframe established by the proficiency testing program. The laboratory processed and reported 187 out of 187 general immunology patient tests from September 2024 to April 2025. The findings include: 1. The PRPTSP and CASPER report were reviewed on December 17, 2025, at 10:00 A.M., from February 2024 to December 2025. 2. The Proficiency Testing Service Program 2024 schedule showed that the deadline for submission of results for the third testing event for Diagnostic Immunology was December 20, 2024. 3. The laboratory obtained a score of 0% for the third testing event for immunoglobulins IgE, Infectious Mononucleosis, Rheumatoid Factor and Rubella. 4. During interview on December 17, 2025, at 10:15 A.M., the laboratory general supervisor confirmed that the laboratory failed to report general immunology proficiency testing results for the third testing event within the timeframe established by the PRPTSP. 5. The laboratory processed and reported 187 out of 187 general immunology patient tests from September 2024 to April 2025. .</p>
<p>D5002</p>	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Bacteriology quality control records review (years 2024-2025) and interview with the laboratory general supervisor on December 17, 2025, at 2:30 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for Bacteriology testing. Refer to D5507.</p>
<p>D5507</p>	<p>BACTERIOLOGY CFR(s): 493.1261(b)(c)</p> <p>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests</p>

are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on Bacteriology quality control (QC) records review (years 2024-2025), the establishment and verification of performance specification, and interviews with the laboratory general supervisor on December 17, 2025, at 11:30 A.M., it was determined that the laboratory did not include a negative control material each day of patient testing for antimicrobial susceptibility testing. The laboratory performance the quality control procedure on a weekly basis. The laboratory processed and reported 107 out of 107 antimicrobial susceptibility testing from June 18, 2025, to December 16, 2025. The findings include: 1. The laboratory uses the VITEK 2 system to perform organism identification and antimicrobial susceptibility testing. 2. The laboratory evaluated and verified the performance specifications for the AST panel XN-806 on October 8, 2024, through January 11, 2025. 3. The review of quality control records showed that the laboratory performed antimicrobial susceptibility quality control testing weekly. 4. The laboratory processed and reported 107 out of 107 patient samples with the AST panel XN-806 from June 18, 2025, to December 16, 2025. 5. During interview on December 17, 2025, 2025, at 11:45 A.M., the laboratory general supervisor confirmed that the laboratory did not include a negative control material for antimicrobial susceptibility testing quality control, each day of use.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on Bacteriology quality control records review (years 2024-2025) and interview with the laboratory general supervisor on December 17, 2025, at 2:30 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(ii)

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), CASPER Report 0155D, Proficiency Testing Service Program 2024 Schedule and laboratory general supervisor interview on December 17,

	<p>2025, at 10:25 A.M, it was determined that the laboratory director failed to ensure that the laboratory general supervisor submitted proficiency testing results for Microbiology (Bacteriology and Parasitology) and Diagnostic Immunology (Syphilis Serology and General Immunology) within the timeframe established by the proficiency testing program. Refer to: D2025, D2052, D2071 and D2081.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 quality control records review (years 2024-2025) and interview with laboratory general supervisor on December 17, 2025, at 2:30 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the Bacteriology quality control requirements. Refer to D6117.</p>
D6117	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on Bacteriology quality control records review (years 2024-2025) and interview with the laboratory general supervisor on December 17, 2025, at 2:30 P.M., it was determined that the laboratory technical supervisor did not ensure that antimicrobial susceptibility quality control procedures were performed each day of testing when the laboratory began with the new antimicrobial susceptibility panel. Refer to D5507.</p>