Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1038041	02/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Fabinael	Carr #2 Km 122 Bo Corrales, Aguadilla, 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 Clnico Fabinael on February 11, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on February 11, 2026.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director on February 11, 2026, at 1:30 p.m., the laboratory director failed to ensure that initial training and semiannual competency evaluations were documented for new moderate complexity testing personnel (MT#2, Form CMS-209) prior to and during the first year of patient testing. The findings include: 1. Review of personnel records showed that the laboratory hired new testing personnel in February 2025. 2. The personnel records did not include documentation of the required competency elements, including: a. Direct observations of routine patient test performance, including patient preparation (if applicable), specimen handling, processing, and testing. b. Monitoring, recording, and reporting test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of instrument maintenance and function checks. e. Assessment of test performance through testing of previously analyzed specimens, internal blind samples, or external proficiency testing samples. 3. During

	interview on February 11, 2026, at 1:45 p.m., the laboratory director confirmed that documentation of required training and semiannual competency evaluations was not performed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the rapid plasma reagin (RPR) quality control (years 2025-2026), Aim RPR method manufacturer's instructions, and laboratory director interview, on February 11, 2026, at 12:30 p.m., it was determined that the laboratory failed to follow the manufacturer's instructions regarding to the needle wash for syphilis serology testing, when 1,626 out of 1,626 patient specimens were tested from January 2, 2025, to February 10, 2026. The findings include: 1. The laboratory uses the Aim RPR method to perform syphilis serology testing. 2. Review of the Aim RPR test manufacturer's instructions showed that the needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. 3. Review of the syphilis serology quality control records showed that the laboratory did not perform or document the required needle cleaning when processed and reported 1,626 out of 1,626 RPR patient specimens from January 2, 2025, to February 10, 2026. 4. The laboratory director confirmed during interview on February 11, 2026, at 12:45 p.m., that the laboratory did not follow the manufacturer's instructions for needle cleaning.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation at the laboratory specimen collection area, review of the patient census report, and interview with the laboratory director on February 11, 2026, at 1:00 p.m., the laboratory used expired specimen collection tubes for patient testing. From February 1, 2026, through February 10, 2026, the laboratory collected and referred thirteen (13) patient specimens using expired specimen collection tubes. The findings include: 1. On February 11, 2026, at 1:00 p.m., observation of the laboratory specimen collection area showed eight (8) Buffered Sodium Citrate (pale blue top) tubes, lot number 5101307, with an expiration date of January 31, 2026. 2. Review of the patient census report showed that six (6) patient specimens were collected and referred for Partial Thromboplastin Time (PTT) testing, and seven (7) patient specimens were collected and referred for Prothrombin Time (PT) testing between February 1, 2026, and February 10, 2026. 3. During interview on February 11, 2026, at 1:19 p.m., the laboratory director confirmed that thirteen (13) coagulation patient specimens (Prothrombin Time [PT] and Partial Thromboplastin Time [PTT]) were collected and referred using expired Buffered Sodium Citrate tubes.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of hematology performance specification records and interview with the laboratory director on February 11, 2026, at 11:40 a.m., the laboratory failed to verify the performance specifications for the remanufactured Medonic M Series Hematology Analyzer prior to performing patient testing and reporting patient test results. The laboratory processed and reported 15,675 Complete Blood Count (CBC) tests from July 2025 through February 2026. The findings include: 1. The laboratory replaced its hematology instrument with a remanufactured Medonic M Series Hematology Analyzer on July 1, 2025. 2. A review of performance specification records showed that the laboratory did not verify the performance specifications (accuracy, precision, reportable range, and verification of reference intervals) prior to placing the Medonic M Series Hematology Analyzer into routine patient testing. 3. During interview on February 11, 2026, at 12:15 p.m., the laboratory director confirmed that the laboratory did not verify the required performance specifications before performing patient testing and reporting patient test results on the Medonic M Series Analyzer. 4. From July 1, 2025, through February 11, 2026, the laboratory processed and reported 15,675 CBC tests using the Medonic M Series Hematology Analyzer.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the lack of performance specification records and interview with the laboratory director on February 11, 2026, at 2:00 p.m., the laboratory director failed to ensure that the performance specifications for the hematology test system were verified prior to patient testing. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 direct observation, review of manufacturer instructions and interviews with the laboratory director on February 11, 2026, at 2:00 p.m., the laboratory director failed to implement adequate controls to prevent the use of expired tubes. Additionally, did not ensure that the laboratory adhered to established protocols for cleaning the needle utilized in the RPR tests. Refer to D5411 and D5417.