Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2000974	01/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Figueroa	Carr Pr-155 Km 58 Hm 5 Barrio Pugnado Adentro, Vega Baja, 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 Figueroa on January 12, 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 January 12, 2026.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on manufacturer's specifications, lack of hematology preventive maintenance records review (10/2025-1/26) and laboratory general supervisor interview on January 12, 2026 at 10:40 AM, the laboratory failed to perform and document the preventive maintenance as required by the manufacturer of the Sysmex XN-550 hematology instrument, when they processed and reported 246 Complete Blood Count (CBC) tests from October 2025 to January 12, 2026. The findings include: 1. The laboratory begin to use the Sysmex XN-550 hematology instrument to perform CBC patient tests in October 2025. 2. . The manufacturer's specifications establishes that the daily and weekly maintenance of the Sysmex XN-550 hematology instrument are the following: shutdown and routine cleaning. 3. On January 12, 2026 at 10:40 AM, review of preventive maintenance records from October 2025 to January 12, 2026 , showed that the laboratory did not perform nor document the daily and monthly preventive maintenance of the hematology instrument. 4. The laboratory processed and reported 302 CBC sample tests from October 2025 to January 12, 2026. 5. The

	laboratory general supervisor confirmed on January 12, 2026, at 10:50 AM, that the laboratory failed to follow the manufacturer's specifications for the preventive maintenance of the Sysmex XN-550 hematology instrument.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (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. This STANDARD is not met as evidenced by: Based on chemistry quality control records review (years 2024 - 2025) and laboratory general supervisor interview on January 12, 2026 at 11:50, the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 840 routine chemistry patient samples from November 3, 2025 to January 12, 2026. The findings include: 1. The laboratory performs chemistry routine chemistry tests by Dimension EXL-200 system. 2. On January 12, 2026 at 11: 50 AM, the chemistry quality control records review (years 2024 - 2025), showed that there was no evaluation of the manufacturer's stated values for the lot numbers CHA26081-A (control level 1), and OCR25112 (control level 2) prior to placing them in routine use on November 3, 2025. 3. The laboratory general supervisor confirmed on January 12, 2026 at 11:55AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for routine chemistry tests performed by the EXL-200 system prior to begin to test patients samples. 4. The laboratory processed and reported 840 routine chemistry patient samples from November 3, 2025 to January 12, 2026.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: A. Based on Mycoplasma pneumoniae quality control records review (year 2025) and laboratory general supervisor interview on January 12, 2026 at 11:10 A.M., the laboratory did not evaluate the new lots of Mycoplasma pneumoniae test for positive and negative reactivity prior to placing it in routine use on September 3, 2025. The findings include: 1. The laboratory performed a Mycoplasma Pneumoniae test by Immuno Card method. 2. The Mycoplasma Pneumoniae quality control records were

reviewed from January 2, 2025 to January 12, 2026 and showed that the laboratory did not evaluate the new lot of Mycoplasma pneumoniae test for positive and negative reactivity prior to placing it in routine use: - Lot Number: 7090304328, Expiration date :10/1/2026, Date opened: 9/3/25, Patient processed and reported: 250 patients 3. The laboratory performed and reported 250 out of 250 Mycoplasma Pneumoniae patient samples from September 3, 2025 to December 13, 2025. 4. The laboratory general supervisor confirmed on January 12, 2026 at 11:15 A.M., that the laboratory did not evaluate the new lot of Mycoplasma Pneumoniae test for positive and negative reactivity prior to placing it in routine use. B. Based on human chorionic gonadotropin (hCG) test quality control records review (year 2025) and laboratory general supervisor interview on January 12, 2026 at 11:30 A.M, that the laboratory did not evaluate the new lots of hCG test for positive and negative reactivity prior to placing it in routine use on October 17, 2025. The findings include: 1. The laboratory performed hCG test by Aimstep method. 2. The hCG quality control test records were reviewed from January 2, 2025 to January 12, 2026 and showed that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use: Lot Number: 43532, Expiration date :4/30/2027, Date opened: 10/17/25. 3. The laboratory performed and reported 12 out of 12 hCG patient samples since October 17, 2025 to December 12, 2025 4. The laboratory general supervisor confirmed on January 12, 2026 at 11:35 A.M., that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use. C. Based on Rapid Plasma Reagin (RPR) test quality control records review (year 2025) and laboratory general supervisor interview on January 12, 2026 at 11:20 A.M, the laboratory did not evaluate the new lots of RPR test for positive and negative reactivity prior to placing it in routine use on August 2025. The findings include: 1. The laboratory performed RPR test by germaine method. 2. The RPR quality control test records were reviewed from January 2, 2025 to January 12, 2026 and showed that the laboratory did not evaluate the new lot of RPR test for positive and negative reactivity prior to placing it in routine use: Lot Number: 501505, Expiration date : 2/28/2026, Date opened: 8/2025. 3. The laboratory performed and reported 210 out of 210 RPR patient samples since August 2025 to December 15, 2025. 4. The laboratory general supervisor confirmed on January 12, 2026 at 11:25 A. M., that the laboratory did not evaluate the new lot of RPR test for positive and negative reactivity prior to placing it in routine use. D. Based on Infectious mononucleosis test (IM test) quality control records review (year 2025) and laboratory general supervisor interview on January 12, 2026 at 11:15 A.M, the laboratory did not evaluate the new lots of IM test for positive and negative reactivity prior to placing it in routine use on December 2025. The findings include: 1. The laboratory performed IM test by germaine method. 2. The IM quality control test records were reviewed from January 2, 2025 to January 12, 2026 and showed that the laboratory did not evaluate the new lot of IM test for positive and negative reactivity prior to placing it in routine use: Lot Number: L5A17BA, Expiration date : 1/27 Date opened: 12/15/25. 3. The laboratory performed and reported 5 out of 5 IM patient samples. 4. The laboratory general supervisor confirmed on January 12, 2026 at 11:15 A.M., that the laboratory did not evaluate the new lot of IM test for positive and negative reactivity prior to placing it in routine use. E. Based on Rheumatoid Arthritis test (RA test) quality control records review (year 2025) and laboratory general supervisor interview on January 12, 2026 at 11:25 A.M, the laboratory did not evaluate the new lots of RA test for positive and negative reactivity prior to placing it in routine use on December 2025. The findings include: 1. The laboratory performed RA test by germaine method. 2. The RA quality control test records were reviewed from January 2, 2025 to January 12, 2026 and showed that the laboratory did not evaluate the new lot of RA test for positive and negative reactivity prior to placing it

	in routine use: Lot Number: 501501, Expiration date : 1/31/26 Date opened: 4/9/25. Lot Number: 516701, Expiration date : 8/31/26 Date opened: 10/22/25. 3. The laboratory performed and reported 34 out of 34 IM patient samples. 4. The laboratory general supervisor confirmed on January 12, 2026 at 11:25 A.M., that the laboratory did not evaluate the new lot of RA test for positive and negative reactivity prior to placing it in routine use.
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 hematology, routine chemistry tests, General Immunology, endocrinology , syphilis serology quality control records and interview with the laboratory general supervisor on January 12, 2026 at 12:30 PM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D5429 , D5469 and D5471.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology, routine chemistry tests , general immunology , endocrinology and syphilis serology quality control records and interview with the laboratory general supervisor on January 12, 2026 at 12:30 PM, the laboratory general supervisor failed to fulfill her responsibilities and duties to ensure compliance with laboratory quality control requirements. Refer to D5429 , D5469 and D5471.