Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1031776	02/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Jireh	Carr #2 Km 18 Hm 6 Bo Mucarabones, Toa Alta, 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 Jireh on February 7, 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 February 7, 2025.
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 personnel records review (years 2023-2024) and laboratory supervisor interview on February 7, 2025 at 10:25 AM, it was determined that the laboratory failed to follow the established schedule for competency evaluation for the technical supervisor, general supervisor, technical consultant, medical technologist and clinical consultant. The finding includes: 1. On February 7, 2025 at 10:20 AM, the laboratory written policies for personnel competency procedures showed that the competency procedures must be performed annually. 2. The person who holds position #3 (CMS-209 Form) was designated as technical supervisor, general supervisor, technical consultant, and medical technologist. The laboratory did not evaluate the competency during years 2023 nor 2024. 3. The clinical consultant competency was not evaluated during years 2023 nor 2024. 4. During the interview on February 7, 2025 at 10:25 AM, the laboratory supervisor confirmed that the technical supervisor, general supervisor, technical consultant, medical technologist and clinical consultant competency evaluations were 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: A. Based on syphilis serology quality control records, manufacturer's instructions review, and laboratory supervisor interview, on February 7, 2025 at 11:56 AM, it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 213 patient specimens were processed and reported from January 1, 2024 to February 7, 2025. The findings include: 1. The laboratory uses the ASI's reagent kit to perform patient syphilis serology test. Review of the ASI's manufacturer's instructions on February 7, 2025 at 11:53 AM, showed that the laboratory must remove and wash the needle at the end of the day. 2. On February 7, 2025 at 11:56 AM the syphilis serology quality control records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported 213 patient specimens from January 1, 2024 to February 7, 2025. 3. The laboratory supervisor confirmed on February 7, 2025 at 12:00 PM, that the laboratory did not follow the manufacturer's instructions related to the needle wash, from January 1, 2024 to February 7, 2025. B. Based on urinalysis instrument Clinitek Status maintenance records, manufacturer's instructions review, and laboratory supervisor interview, on February 7, 2025 at 11:45 AM, it was determined that the laboratory failed to perform the weekly maintenance of the instrument, when 3,108 patient specimens were processed and reported for urinalysis tests from January 1, 2024 to February 7, 2025. The findings include: 1. The laboratory uses the Clinitek Status instrument to perform patient's urinalysis tests. 2. On February 7, 2025 at 11:45 AM, the Clinitek Status maintenance records were reviewed, and showed that the laboratory failed to perform the following weekly maintenance: cleaning of the test table and test table insert, cleaning the white calibration bar, and disinfect the external surface of the instrument, when they processed and reported 3,108 patient specimens from January 1, 2024 to February 7, 2025. 3. The laboratory supervisor confirmed on February 7, 2025 at 11:49 AM, that the laboratory did not perform the weekly maintenance of the urinalysis instrument.
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 supervisor interview on February 7,

	2025 at 1:37 PM, it was determined that the laboratory failed to monitor and document the room temperature, when 521 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test from January 1, 2024 to February 7, 2025. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. On February 7, 2025 at 1:34 PM the manufacturer's instructions were reviewed, and it establishes to perform the test procedures at room temperature from 22 to 25 C. 3. On February 7, 2025 at 1:37 PM, 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 1, 2024 to February 7, 2025. 4. The laboratory supervisor confirmed on February 7, 2025 at 1:42 PM, that the laboratory did not monitor nor document the room temperature when they processed the patient's specimens for Mycoplasma pneumoniae IgM test. 5. The laboratory processed and reported 521 patient samples for Mycoplasma pneumoniae IgM test from January 1, 2024 to February 7, 2025.
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 review of the hematology DxH 520 instrument performance verification results and laboratory supervisor interview on February 7, 2025 at 10:41 AM, it was determined that the laboratory failed to evaluate the instrument's obtained results. The findings include: 1. On February 7, 2025 at 10:40 AM, review of the Beckman Coulter Installation Work Order Report (#WO-06194716) showed, that the laboratory installed the DxH 520 hematology system on November 22, 2023. 2. On February 7, 2025 at 10:41 AM, review of the DxH 520 instrument performance verification results did not reflect the evaluation and signature of the laboratory director prior to begin to test Complete Blood Count (CBC) patient samples. 3. The laboratory supervisor confirmed on February 7, 2025 at 10:46 AM that the laboratory director did not evaluate and sign the performance verification of the DxH 520 hematology system. 4. The laboratory processed and reported 4,554 CBC tests on the DxH 520 hematology system from December 1, 2023 to February 7, 2025.
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 urinalysis quality control records review and laboratory supervisor interview on February 7, 2024 at 11:32 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 157 patient samples from September 24, 2024 to February 7, 2025. The findings include: 1. The laboratory performs urinalysis tests with the Clinitek Status system and uses Thermo Scientific MAS UA control material. 2. The urinalysis quality control records reviewed on February 7, 2024 at 11:32 AM, from September 24, 2024 to February 7, 2025, showed that there was no evaluation of the manufacturer's stated values for the current lot number UB152601M prior to place it in routine use on September 24, 2024. 3. The laboratory supervisor stated on February 7, 2024 at 11:32 AM, that no evaluations of the current lot of control material were performed prior to place it in routine use. 4. The laboratory supervisor confirmed on February 7, 2024 at 11:37 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests performed by the Clinitek Status system, when they processed and reported 157 patient samples from from September 24, 2024 to February 7, 2025.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory written policies, personnel competency records, and interview with the laboratory supervisor on February 7, 2025 at 10:25 AM; it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the personnel competency procedures requirements. Refer to D5209.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on review of the quality control records, manufacturer's instructions review,

	and interview with the laboratory supervisor on February 7, 2025 at 1:42 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 D5411, and D5413.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 review of the hematology instrument performance verification results, urinalysis quality control records, and interview with the laboratory supervisor on February 7, 2025 at 11:37 AM; it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the hematology performance verification results of the new instrument, and urinalysis quality control requirements. Refer to D5421, and D5469.