Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0862901	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Paseos Ii	Calle Bolivia 76 Suite 102, Hato Rey, 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
D2071	SYPHILIS SEROLOGY CFR(s): 493.835(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 Puerto Rico Proficiency Testing Program records review (years 2020 - 2021) and laboratory general supervisor interview on February 16, 2022 , it was determined that the laboratory obtained a test result score of 0% for the general immunology first testing event of year 2021. The finding includes: 1. The Puerto Rico Proficiency testing records were reviewed from February 2020 to December 2021 on February 16, 2022 at 9:15 AM. 2. For the general immunology, first testing event of year 2021, the report deadline was April 30, 2021. 3. The laboratory did not submit the results of the first testing event of year 2021 for general immunology on the date established by the Puerto Rico Proficiency Testing Program. 4. The laboratory general supervisor confirmed on February 16, 2022 at 9:35 A.M. that the laboratory did not report the general immunology proficiency testing results of the first testing event 2021 within the time frame established by the Proficiency Testing Program. The laboratory received a testing score of 0% in the first testing event of year 2021 for general immunology.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on manufacturer's instructions, endocrinology quality control records review (years 2020-2022) and laboratory general supervisor interview on February 16, 2022 , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen was tested for hCG qualitative (human chorionic gonadotropic) by Clarity Pregnancy One Step Rapid Test kit. The findings include: 1. The laboratory uses Clarity Pregnancy One Step Rapid Test kit when patient specimen were tested for hCG qualitative (human chorionic gonadotropic since January 2021. 2. The manufacturer's instructions on February 16, 2022 at 11:00 AM showed that a internal control was part of the testing cartridge. The manufacturer established that the internal control is a way used for validate the procedure: "A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural tecnique. The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T) you should repeat the test with a new test strip". 3. The endocrinology quality control records review from February 26, 2021 to February 11, 2022 on February 16, 2022 at 11:10 A.M., the records showed that the laboratory did not document the internal control which each on of the fifty seven (57) patiens's specimen tested for hCG qualitative during the above mentioned period of time. 4. The laboratory general supervisor stated on February 16, 2022 at 11:15 A.M. that the laboratory failed to document the internal control results with each sample patient test. B. Based on urinalysis quality control records review (years 2021-2022) and laboratory general supervisor interview on February 16, 2022 , it was determined that the laboratory failed to follow requirements for quality control when manual microscopic urinalysis examination were performed. 1. The laboratory uses urocheck strips for urinalysis patient samples tests. 2. Urinalysis quality control records were reviewed from January 2021 to January 2022 on February 16, 2022 at 10:00 AM. 3. The records showed that the laboratory did not include a microscopic negative control material when performed manual microscopic urinalysis examination since January 2021. 4. The laboratory performed and reported (993) nine hundred ninty three urinalysis patient samples in January 2021 to January 2022. 5. The laboratory general supervisor confirmed on February 16, 2022 at 10:15 A.M. that the laboratory did not include a microscopic negative control material each day of testing when performed manual microscopic urinalysis examination since January 2021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2020-2021) and laboratory general supervisor interview on February 16, 2022 at 9:35 A.M., it was determined that the laboratory director failed to ensure that the general

	immunology proficiency test report for first testing event of year 2021 were submitted within the established time frame. Refer to D2071.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, endocrinology quality control records review (years 2020-2022), urinalysis quality control (years 2021-2022) and laboratory general supervisor interview on February 16, 2022 at 11:50 A.M., it was determined that laboratory director failed to ensure that the quality control requirements were met. Refer to D5449.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on manufacturer's instruction, endrocrinology quality control records review (years 2020-2022), urinalysis quality control (years 2021-2022) and laboratory general supervisor interview on February 16, 2022 at 11:50 A.M., it was determined that testing personnel failed to follow quality control procedures. Refer to D5449.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on personnel records files review (years 2020-2021) and the laboratory general supervisor interview on February 16, 2022 at 11:50 AM, it was determined that the laboratory failed to ensure that a comprehensive mechanism is used to evaluate the competency of the testing personnel. The finding includes: 1. The laboratory testing personnel includes on medical technologist and technical supervisor (MT#1) and second medical technologist (MT #2) 2. The testing personnel records for MT #1 and

	MT #2 showed on February 16, 2022 at 11:50 A.M that the laboratory did not include the following requirements in his competency evaluation performed in January 2021 and January 2022: a. Direct observations of routine patient test performance , including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing record and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of problem solving skills.
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 manufacturer's instructions, endocrinology quality control records review (years 2020-2022), urnalysis quality control (years 2021-2022) and laboratory general supervisor interview on February 16, 2022 at 11:50 AM, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5449.