Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658052	10/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Canovanas	Calle Palmer # 8, Esq Calderon Mojica, Canovanas, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) testing records review from February 2020 to September 2021 and laboratory director interview on October 15, 2021 at 9:28 AM, it was determined that the laboratory failed to maintain a copy of the proficiency testing event records. The findings include: 1. The PRPTP records were reviewed from February 2020 to September 2021. 2. On October 15, 2021, the PRPTP records showed that the laboratory did not have the following proficiency testing records for November 2020 and December 2020 testing events. 3. The laboratory director confirmed on October 15, 2021 at 9:28 AM, that those proficiency testing event records were not available in the laboratory. 4. This deficiency was cited on May 29, 2019.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2020 to September 2021 and laboratory director interview on October 15, 2021 at 9:35 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. The PRPTP records and results were reviewed since February 2020 to September 2021. 2. Review of proficiency testing (PRPTP) records showed that the laboratory obtained unsatisfactory results of 0 percent in Alanine Aminotranferase (ALT), Albumin, Alkaline Phosphate, Aspartate Aminotranferase (AST), Bilirubin Total, Calcium, Chloride, Cholesterol Total, Cholesterol High Density (HDL), Creatinine, Glucose Potassium, Sodium, Total Protein, Triglycerides and Urea Nitrogen (BUN) tests in May 2021 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory director confirmed on October 15, 2021 at 9:35 AM, that the laboratory did not take corrective actions on May 2021 testing event.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review from February 2020 to September 2021 and laboratory director interview on October 15, 2021 at 9:35 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in endocrinology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2020 to December 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in T3 uptake, Thyroxine (T4), Thyroid Stimulating Hormone (TSH) and Prostate Specific Antigen (PSA) tests in June 2020 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory director confirmed on October 15, 2021 at 9:35 AM, that the laboratory did not take corrective actions on June 2020 testing event.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on hematology quality control records review from January 4, 2020 to October 15, 2021 and laboratory director interview on October 15, 2021 at 11:48 AM, it was determined that the laboratory failed to retain the hematology quality control graphs. The finding includes: 1. The laboratory did not maintain the hematology quality control graphs records from May 28, 2021 to October 15, 2021. Refer to D5481. 2. The laboratory director confirmed on October 15, 2021 at 11:48 AM, that those quality control records were not available. 3. This deficiency was cited on May 29, 2019.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records from February 2020 to September 2021 and laboratory director interview on October 15, 2021 at 9: 48 AM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. The PRPTP proficiency testing records were reviewed from February 2020 to September 2021. 2. The laboratory did not have the proficiency testing (PRPTP) records scores the June 2020 (PRPTP - second testing event) and May 2021 (PRPTP - second testing event). 3. The laboratory director confirmed on October 15, 2021 at 9:48 AM, that the laboratory did not have these PRPTP testing records. 4. This deficiency was cited on May 29, 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from March 4, 2020 to October 15, 2021 and laboratory director interview on October 15, 2021 at 10:54 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 614 out of 614 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 4, 2020 to October 15, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On October 15, 2021 at 10:54 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 4, 2020 to October 15, 2021. 3. The laboratory director confirmed on October 15, 2021 at 10:54 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 614 out of 614 patients specimens for mycoplasma test by Immuno Card Meridian method from March 4, 2020 to October 15, 2021.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on hematology quality control records reviewed from January 2020 to October 15, 2021 and laboratory director interview on October 15, 2021 at 10:35 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the tests processed by the Coulter AcT5 Diff system. The findings include: 1. The quality control records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the tests by the Coulter AcT5 Diff system since December 17, 2020. 2. The laboratory director confirmed on October 15, 2021 at 10:35 AM, that the laboratory did not performed the calibration verification procedures for the hematology tests since December 17, 2020. 3. The laboratory processed and reported 7,200 out of 7,2002 hematology

	patients specimens tests by the Coulter AcT5 Diff system from December 17, 2021 to October 15, 2021.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review from January 4, 2020 to October 15, 2021 and laboratory director interview on October 15, 2021 at 11:38 AM, it was determined that the laboratory failed to document the hematology control materials results in quality control charts to ensure that those control values meet the laboratory's criteria for acceptability before reporting patient test results. The findings include: 1. The laboratory processed the Cell Blood Count (CBC) tests by the Coulter AcT5 Diff hematology system. 2. The hematology quality control record showed that the laboratory did not document the hematology control materials results in the quality control charts every day of testing from May 28, 2021 to October 15, 2021. 3. From May 28, 2021 to October 15, 2021, the laboratory processed and reported 1,484 out of 1,484 patients specimens for CBC tests. 4. The laboratory director confirmed on October 15, 2021 at 11:38 AM, that the laboratory processed and reported 1,484 patients specimens for CBC, but the hematology quality control chart were not available since May 28, 2021.
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 Puerto Rico Proficiency Testing Program (PRPTP) records from February 2020 to September 2021, general immunology, hematology quality control records review and laboratory director interview on October 15, 2021 at 1:25 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory proficiency testing records, analytical system requirements (general immunology and hematology quality control records) and competency evaluations of the clinical consultant. Refer to D6079, D6091, D6093 and D6103.
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 lack of hematology quality control graphs from May 28, 2021 to October 15, 2021, lack of proficiency testing records (November 2020 and December 2020) and laboratory director interview on October 15, 2021 at 11:55 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory's records retention requirements. Refer to D3031 (Proficiency Testing Program records retention). Refer to D3037 (Quality Control records retention).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2020 to September 2021 and laboratory director interview on October 15, 2021 at 10:40 AM, it was determined that the laboratory failed to ensure that corrective actions were documented when the laboratory to failed obtain an acceptable participation for endocrinology and routine chemistry tests. Refer to D2094 (did not take nor document a corrective actions for routine chemistry tests during the PRPTP second testing of year 2021). Refer to D2105 (did not take nor document corrective actions for endocrinology tests during the PRPTP second testing event of year 2020).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 general immunology and hematology quality control records review from January 4, 2020 to October 15, 2021 and laboratory director interview on October 15, 2021 at 11:50 AM, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5403 (did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method). Refer to D5439 (did not perform at least every 6 months the calibration verification procedures for the tests by the Coulter AcT5 Diff system). Refer to D5481 (did not document the hematology control materials results in the quality control charts every day of testing).

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 review and laboratory director interview on October 15, 2021 at 9:22 AM, it was determined that the laboratory failed to follow the written procedures to monitor and ensure the competency evaluations each year of the Clinical Consultant. The finding includes: 1. The personnel records showed that the laboratory director did not evaluated annually the competence of the Clinical Consultant. The last competence in records was performed on January 4, 2020.