Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667456	01/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Ensenadeno	J9 Com El Batey, Bo Ensenada, Ensenada, 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) records review from February 2016 to December 2017 and laboratory general supervisor and testing personnel interview on January 17, 2018 at 9:48 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Review of PRPTP testing records from February 2016 to December 2017, showed that the laboratory did not maintain the following proficiency testing event records: March 2016, April 2016, June 2016, July 2016, August 2016, November 2016, December 2016 and March 2017. 2. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory did not maintain these proficiency testing event records.
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 2016 to December 2017 and laboratory general supervisor interview at 9:54 AM on January 17, 2018, 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. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to December 2017. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in Alanine Aminotranferase (ALT), Albumin, Alkaline Phosphate, Aspartate Aminotranferase (AST), Bilirubin, Calcium, Chloride, Cholesterol, Cholesterol High Density (HDL), Creatinine Kinase, Glucose, Potassium, Sodium, Total Protein, Triglycerides, Urea Nitrogen (BUN) and Uric Acid tests in June 2016 (PRPTP - second testing event). No remedial actions were taken. 3. The general supervisor confirmed at 9:54 AM on January 17, 2018, that the laboratory did not perform and report these tests to PRPTP.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2016 to December 2017 and laboratory general supervisor interview at 9:54 AM on January 17, 2018, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 year. Refer D3037.
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 2016 to December 2017 and laboratory general supervisor interview on January 17,

	2018 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. Proficiency Testing records were reviewed from February 2016 to December 2017. 2. The laboratory did not have the proficiency testing records nor testing scores from March 2016 (PRPTP - first testing event), April 2016 (PRPTP - first testing event), June 2016 (PRPTP - second testing event), July 2016 (PRPTP - second testing event), August 2016 (PRPTP- second testing event), November 2016 (PRPTP - third testing event), December 2016 (PRPTP - third testing event) and March 2017 (PRPTP - first testing event). 3. The laboratory general supervisor confirmed on January 17, 2018 at 9:54 AM, that the laboratory did not have these PRPTP testing records.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: 1. Based on urinalysis quality control records review from January 2016 to January 2017 and laboratory general supervisor interview on January 17, 2018 at 11:52 AM, it was determined that the laboratory failed to perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. The findings include: a. The laboratory began to use the Clinitek 500 urinalysis system on July 1, 2017. b. From July 1, 2017 to January 17, 2018, the records showed that the laboratory did not verify the precision, calibration, comparison test, manufacturer's reference intervals (normal values) appropriate for the laboratory's patient's samples. c. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory did not perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. d. The laboratory perform 146 run of urinalysis tests from July 1, 2017 to January 17, 2018. 2. Based on virology quality control records reviewed January 3, 2017 to January 17, 2018 and laboratory general supervisor interview on January 17, 2018 at 11:00 AM, it was determined that the laboratory failed to perform the evaluation of the performance specifications of the virology method (Influenza A/B OSOM). The findings include: 1. The laboratory begin to performed the Influenza A/B tests by OSOM method from January 3, 2017. 2. From January 3, 2017 to January 17, 2018, the records showed that the laboratory did not verify the performance specifications of the new test. 3. The laboratory processed and reported 152 Influenza A/B tests since January 3, 2017. 4. The laboratory general supervisor confirmed on January 17, 2018 that the laboratory did not perform the evaluation of performance specifications of the Influenza A/B (OSOM) method.
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 review from January 2016 to January 17, 2018 and laboratory general supervisor interview at 10:25 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Sysmex XP-300 system. The findings include: 1. The laboratory uses a Sysmex XP-300 system for hematology tests. 2. Review the hematology quality control records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the hematology tests processed by Sysmex XP-300 system since June 21, 2016. 3. The laboratory general supervisor stated on January 17, 2018 at 10:25 AM, that the laboratory did not perform at least 6 months the calibration verification procedures for then hematology tests by the Sysmex XP-300 system.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review and laboratory general supervisor interview on January 17, 2018 at 10:32 AM, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. The findings include: 1. The Monocol/lex manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 saline dilution due to a prozone phenomena. 2. From June 17, 2016 to August 9, 2017, the general immunology quality control records showed that the laboratory did not check 10 out of 10 patient's specimens at a 1:10 dilution before it reported as negative Monotest on 06/17/2016 (ID #1842), 11/12/2016 (ID # 3762), 02/24/2017 (ID # 5197), 03/04/2017 (ID # 5468), 04/11/2017 (ID # 5867), 04/27/2017 (ID # 6044), 06/10/2017 (ID # 6560), 06/20/2017 (ID # 6679), 08/05/2017 (ID # 7259) and 08/09/2017 (ID # 7332). 3. The

	laboratory general supervisor confirmed on January 17, 2018 at 10:32 AM, that the MONO testing records did not include the 1:10 dilution results recorded.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review and laboratory general supervisor interview on January 17, 2018 at 11:42 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. Refer to D5421 (1). b. to perform the evaluation of the performance specifications of the virology method (Influenza A/B OSOM). Refer to D5421 (2). c. to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Sysmex XP-300 system. Refer to D5439. d. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. Refer to D5479.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: 1. Based on hematology quality controls records review from January 2016 to January 17, 2018 and laboratory general supervisor interview on January 17, 2018 at 11:12 AM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values. The finding includes: a. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory failed to evaluate twice a year the relationship between the automatic and manual calculation of the hematology media (MCV, MCH and MCHC) calculated values since Janury 2017. 2. Based on routine chemistry quality controls records review from January 2016 to January 17, 2018 and laboratory general supervisor interview on January 17, 2018 at 11:12 AM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation

	of the routine chemistry ratios (A/G, BUN/Creatinne, Chol/HDL, LDL/HDL) calculated values. The finding includes: a. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory failed to evaluate twice a year the relationship between the automatic and manual calculation of the routine chemistry ratios (A/G, BUN/Creatinine, Chol/HDL, LDL/HDL) calculated values since January 2017.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on Quality Assessment records review (QA) and laboratory general supervisor interview on January 17, 2018 at 11:45 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: Turn Around Time. The findings include: 1. The Quality Assessment procedure manual showed that evaluations of the laboratory turn around time (TAT) annually. 2. The laboratory did not evaluate the turn around time since January 2016. 3. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory did not evaluate the turn around time (TAT) since January 2016.
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 review, quality control records review and laboratory general supervisor interview on January 17, 2018 at 10:25 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing requirements, laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director failed to maintain the proficiency testing event records,take and document corrective actions and retain all proficiency testing events records for at least 2 year. Refer to D2015, D2094 and D3037. 2. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D6093 and D6094.
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 Puerto Rico Proficiency Testing Program (PRPTP) records and laboratory general supervisor interview at 9:48 AM on Janaury 17, 2018, it was determined that the laboratory director failed to fulfill his responsabilities and duties to ensure compliance with the laboratory retention requirements. Refer D3037.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review and laboratory general supervisor interview on January 17, 2018 at 9:54 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2016 to December 2017. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in Alanine Aminotranferase (ALT), Albumin, Alkaline Phosphate, Aspartate Aminotranferase (AST), Bilirubin, Calcium, Chloride, Cholesterol, Cholesterol High Density (HDL), Creatinine Kinase, Glucose, Potassium, Sodium, Total Protein, Triglycerides, Urea Nitrogen (BUN) and Uric Acid tests in June 2016 (PRPTP - second testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on January 17, 2018, that the laboratory did not take corrective actions in this testing event. Refer to D2094.
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 quality control records review and laboratory general supervisor interview on January 17, 2018 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. Refer to D5421 (1). b. to perform the evaluation of the performance specifications of the virology method (Influenza A/B OSOM). Refer to D5421 (2). c. to perform at

	least every 6 months the calibration verification procedures for the hematology tests processed by the Sysmex XP-300 system. Refer to D5439. d. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. Refer to D5479.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment (QA) records review and laboratory general supervisor interview on January 17, 2018 at 11:48 AM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems and postanalytic. Refer to D5791 and D5891.
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 general supervisor interview on January 17, 2018 at 10:48 AM, it was determined that the laboratory failed to follow the written procedures to monitor and ensure the competency evaluations of the testing personnel and Clinical Consultant. The finding includes: 1. The laboratory schedule for testing personnel and clinical consultant competence evaluation showed that it must be performed every year. 2. The laboratory did not perform the testing personnel (MT # 1 and MT #2) and clinical consultant (MD #4938)competence evaluation since January 2017.
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 quality control records review and laboratory general supervisor interview on January 17, 2018 at 11:50 AM, it was determined that the general supervisor failed to perform day to day supervision for the supervision for the personnel that

	performing testing and reporting test results. The findings include: 1. The laboratory general supervisor did not evaluate aspects regarding: a. to perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. Refer to D5421 (1). b. to perform the evaluation of the performance specifications of the virology method (Influenza A/B OSOM). Refer to D5421 (2). c. to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Sysmex XP-300 system. Refer to D5439. d. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. Refer to D5479.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 quality control records review and laboratory general supervisor interview on January 17, 2018 at 11:48 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to perform the evaluation of the performance specifications of the Clinitek 500 urinalysis system. Refer to D5421 (1). b. to perform the evaluation of the performance specifications of the virology method (Influenza A/B OSOM). Refer to D5421 (2). c. to perform at least every 6 months the calibration verification procedures for the hematology tests processed by the Sysmex XP-300 system. Refer to D5439. d. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocolex method. Refer to D5479.