Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658313	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Hyde Park	Calle Las Marias #238, Urb Hyde Park, Rio Piedras, 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 2017 to August 2018 and laboratory director interview on September 5, 2018 at 10:12 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were review from February 2017, to August 2018. 2. Review of proficiency testing records showed that the laboratory did not maintain the following proficiency testing event records: June 2017 (PRPTP second testing event for routine chemistry) and July 2017 (PRPTP second testing event for hematology). 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not maintain these proficiency testing event records.
D2072	SYPHILIS SEROLOGY CFR(s): 493.835(d)

	(1) For any unsatisfactory 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 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 2017 to August 2018 and laboratory director interview on September 5, 2018 at 10:15 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in syphilis serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were review from February 2017, to August 2018. 2. Review of proficiency testing records showed that the laboratory obtained unsatisfactory results of 60 per cent in syphilis serology quantitative tests in April 2018 (PRPTP first testing event for syphilis serology). No remedial actions were taken. 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not take corrective actions on April 2018 testing event.
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 2017 to August 2018 and laboratory director interview on September 5, 2018 at 10:15 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. Puerto Rico Proficiency Testing Program (PRPTP) records and results were review from February 2017, to August 2018. 2. Review of proficiency testing records showed that the laboratory obtained unsatisfactory results of 0 per cent in routine chemistry tests (Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphate, Aspartate Aminotransferase (AST), Cholesterol - Total, Cholesterol High Density Lipoprotein (HDL), Creatinine, Glucose, Lactase Dehydrogenase (LDH), Total Protein, Triglycerides, Uric Acid, and Phosphorus) in June 2018 (PRPTP second testing event for routine chemistry). No remedial actions were taken. 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not take corrective actions on June 2018 testing event.
D2128	HEMATOLOGY CFR(s): 493.851(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 2017 to August 2018 and laboratory director interview on September 5, 2018 at 10:15 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were review from February 2017, to August 2018. 2. Review of proficiency testing records showed that the laboratory obtained unsatisfactory results of 40 per cent in hematology (Partial Thromboplastin Time - PTT) tests in March 2017 (PRPTP first testing event for hematology). No remedial actions were taken. 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not take corrective actions on March 2017 testing event.
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, syphilis serology quality control records review and laboratory director interview on September 5, 2018 at 10:35 AM, it was determined that the laboratory failed to included meet the requirements for syphilis serology by Rapid Plasma Reagin (RPR) tests. Refer to D5451.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review from January 4, 2018 to September 4, 2018 and laboratory director interview on September 5, 2018 at 10:33 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when patients were tested for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. The findings include: 1. The laboratory performed Rapid Plasma Reagin (RPR) by

	ASI RPR Reagents set. 2. Review of syphilis serology quality control from January 4, 2018 to September 4, 2018, showed that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when the following patients specimen were processed and report on May 15, 2018 (ID # 2018-321, R 1:32 dils, ID # 2018-323, R 1:16 dils, ID # 2018- 324, R 1:8 dils) and August 17, 2018 (ID # 2018 - 711 R 1:32 dils, ID # 2018 - 712 R 1:64 dils, ID # 2018 - 713 R 1:128 dils). 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when patients specimens were tested for syphilis serology quantitative those days.
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 manufacturer's instructions, syphilis serology quality control records review and laboratory director interview on September 5, 2018 at 10:33 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: 1. failed to follow the manufacturer's instructions when patient specimens were tested for quantitative Rapid Plasma Reagin (RPR) by ASI. Refer to D5451.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, quality control records review and laboratory director interview on September 5, 2018 at 11:58 AM, it was determined that the laboratory director failed to fulfil her responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the requirements for analytical systems and quality assessment requirements. Refer to D6019, D6020 and D6021.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed

	when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2017 to August 2018 and laboratory director interview on September 5, 2018 at 10:15 AM, it was determined that the laboratory failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were review from February 2017 to August 2018. 2. Review of proficiency testing records showed that the laboratory obtained unsatisfactory results of 60 per cent in syphilis serology quantitative tests in April 2018 (PRPTP first testing event for syphilis serology), 0 per cent in routine chemistry tests (Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphate, Aspartate Aminotransferase (AST), Cholesterol - Total, Cholesterol High Density Lipoprotein (HDL), Creatinine, Glucose, Lactase Dehydrogenase (LDH), Total Protein, Triglycerides, Uric Acid, and Phosphorus) in June 2018 (PRPTP second testing event for routine chemistry) and 40 per cent in hematology tests (Partial Thromboplastin Time - PTT) in March 2017 (PRPTP first testing event for hematology). No remedial actions were taken. 3. The laboratory director confirmed on September 5, 2018, that the laboratory did not take corrective actions on those testing event. Refer to D2072, D2094 and D2128.
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, quality control records review and laboratory director interview on August 31, 2018 at 11:56 AM, it was determined that the laboratory director failed to ensure compliance with requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. failed to follow the manufacturer's instructions when patient specimens were tested for quantitative Rapid Plasma Reagin (RPR) by ASI. Refer to D5451.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on Quality Assessment (QA) records review and laboratory director interview on August 31, 2018 at 11:58 AM, it was determined that the laboratory director failed to ensure compliance with QA requirements. The finding includes: 1. The laboratory director did not evaluate the established Quality Assessment Program to monitor and document the following requirement for analytic systems: a. failed to follow the manufacturer's instructions when patient specimens were tested for quantitative Rapid Plasma Regain (RPR) by ASI. Refer to D5451.
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 instructions, syphilis quality control records review and laboratory director interview on September 5, 2018 at 11:58 AM, it was determined that the laboratory testing personnel failed to follow the quality control requirements. The finding includes: 1. The laboratory testing personnel failed to following quality control procedures: a. failed to follow the manufacturer's instructions when patient specimens were tested for quantitative Rapid Plasma Reagin (RPR) by ASI. Refer to D5451.