Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669530	01/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Los Robles	#308 Americo Miranda Ave, 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
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2016-2017) and laboratory general supervisor interview on January 19, 2018 at 10:00 A.M., it was determined that the laboratory failed to participate in the Bacteriology first testing event performed in April 2016. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The laboratory did not participate in the first testing event of Syphilis Serology (April 2016) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on January 19, 2018 at 10: 00 A.M., that the laboratory failed to participate in the first testing event of Bacteriology test performed in April 2016.
D2026	BACTERIOLOGY CFR(s): 493.823(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)

	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 and laboratory general supervisor interview on January 19, 2018 at 9:30 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in bacteriology (susceptibility test) specialty. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2016 to July 2017. 2. Review of Proficiency Testing records showed that the laboratory failed to take remedial actions when obtained unsatisfactory results in Bacteriology specialty (Susceptibility tests) the following events: August 2016 - 50 %, December 2016- 0 % April 2017-50% 3. The general supervisor confirmed that the laboratory failed to take remedial actions when obtained unsatisfactory results in Bacteriology specialty (Susceptibility tests) since August 2016.
D2067	SYPHILIS SEROLOGY CFR(s): 493.835(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2016-2017) and laboratory general supervisor interview on January 19, 2018 at 10:00 A.M., it was determined that the laboratory failed to participate in the Syphilis Serology first testing event performed in April 2016. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The laboratory did not participate in the first testing event of Syphilis Serology (April 2016) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on January 19, 2018 at 10: 00 A.M., that the laboratory failed to participate in the first testing event of Syphilis Serology test performed in April 2016.
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of

	patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2016-2017) and laboratory general supervisor interview on January 19, 2018 at 10:00 A.M., it was determined that the laboratory failed to participate in the General Imunology first testing event performed in April 2016. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The laboratory did not participate in the first testing event of General Imunology (April 2016) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on January 19, 2018 at 10: 00 A.M., that the laboratory failed to participate in the first testing event of General Imunology test performed in April 2016.
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 lack of routine chemistry quality control records, hematology and routine chemistry calibration verification records, laboratory director and laboratory general supervisor interview at 11:30 a.m. on January 19, 2018, it was determined that the laboratory failed to keep quality control records and calibration verifications records . Refer D3031.
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: 1. Based on routine chemistry quality controls records reviewed (2016-2017) , laboratory director and laboratory general supervisor interview on January 19, 2018 at 11:00 A.M., it was determined that the laboratory failed to retain the routine chemistry quality control records. The findings include: a. The laboratory performed routine chemistry tests by Daytona system. b. The laboratory did not have available quality control records since January 2016. c. The laboratory general supervisor confirmed on January 19, 2018 at 11:00 A.M. that the laboratory did not have available the quality

	control records for routine chemistry tests since January 2016. d. The laboratory processed and reported patient's sample since 2016. 2. Based on lack of routine chemistry calibration verifications records (2016-2017) , laboratory director and laboratory general supervisor interview on January 19, 2018 at 11:00 A.M., it was determined that the laboratory failed to retain the routine chemistry calibration verifications records. The findings include: a. The laboratory performed routine chemistry tests by Daytona system. b. The laboratory did not have available calibration verifications records since January 2016. c. The laboratory general supervisor confirmed on January 19, 2018 at 11:00 A.M. that the laboratory did not have available the calibration verifications records for routine chemistry tests since January 2016. 3. Based on lack of hematology calibration records (2016) , laboratory director and laboratory general supervisor interview on January 19, 2018 at 11:00 A. M., it was determined that the laboratory failed to retain the hematology calibration records. The findings include: a. The laboratory performed hematology tests by Medonic system. b. The laboratory did not have available hematology calibration records of the year 2016. c. The laboratory general supervisor confirmed on January 19, 2018 at 11:00 A.M. that the laboratory did not have available the calibration records of the year 2016 for hematology tests .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of hematology calibration procedures records and laboratory general supervisor interview on January 19, 2018 at 10:00 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the hematology tests performed by the Medonic M16M system. The findings include: 1. The laboratory did not perform at least every 6 months the calibration verification procedures for hematology tests since January 2016. 2. The laboratory general laboratory stated on 12/03/2015 at 10:29 AM, that the laboratory did not have available the hematology calibration verification procedures since January 2016. 3. From 2016 to 2017, the laboratory processed and report approximately 4,425 patients specimens by the Medonic M16M system. 4. This deficiency was cited on the last survey performed on December 3, 2015.
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 control records review in 2016-2017 and laboratory director and laboratory general supervisor interview on January 19, 2018 at 11:30 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. The laboratory failed to perform at least every 6 months the calibration verification procedures for the hematology tests performed by the Medonic M16M system. Refer to D5437.
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 quality control records review , laboratory director and laboratory supervisor interview on January 19, 2018 at 11:30 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control , proficiency testing and retention requirements. Refer to D6079, D6089 and D6093.
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 records and laboratory general supervisor interview at 11:30 a.m. on January 19, 2018, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory retention requirements. Refer D3031.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

	This STANDARD is not met as evidenced by: Based on proficiency testing records review and laboratory general supervisor interview on January 19, 2018 at 10:00 A.M, it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2021, D2026, D2067 and D2077.
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 hematology quality control records review and laboratory general supervisor interview on January 18, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not ensure quality control procedures for hematology tests. Refer to D5437.
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 , laboratory director and general supervisor interview on January 1, 2018 at 11:30 A.M., it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5437.