Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0883089	02/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cdt Del Municipio De Canovanas	Calle Corchado Final, 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 lack of Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at 9:35 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Proficiency Testing records were reviewed from February 2017 to December 2108. 2. Review of proficiency testing records from February 2017 to December 2018, showed that the laboratory did not maintain the following proficiency testing event records from February 2018 to December 2018. 3. The laboratory director and testing personnel confirmed on February 6, 2019, that the laboratory did not maintain these proficiency testing event records. 4. This deficiency was cited on February 14, 2017.
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 December 2018 and laboratory director and testing personnel interview on February 6, 2019, 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 records and results were reviewed from February 2017 to December 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Hematology Cell Identification tests on March 2017 (PRPTP First testing event). No remedial actions were taken. 3. The laboratory director and testing personnel confirmed on February 2019, that the laboratory did not take corrective actions on this testing event.
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 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at 9:54 AM, it was determined that the laboratory failed to keep the proficiency testing records and hematology quality control records for at least 2 year. Refer D3031 and D3037.
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 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at

	10:39 AM, it was determined that the laboratory failed to retain the hematology quality control (Levy-Jennings graphs) for at least 2 years. The finding includes: 1. The hematology quality control were reviewed since January 2, 2017. 2. The laboratory did not maintain the hematology quality control records (Levy-Jennings graphs) on July 2018 (283 patient's tests), August 2018 (296 patient's tests), October 2018 (370 patient's tests), November 2018 (289 patient's tests) and December 2018 (277 patients tests). 3. The laboratory director and testing personnel confirmed on February 6, 2019, that the laboratory did not maintain those quality control records. 4. This deficiency was cited on February 14, 2017.
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 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 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. Puerto Rico Proficiency Testing Program (PRPTP) records were reviewed from February 2017 to December 2018. 2. The laboratory did not have the proficiency testing records nor testing scores from February 2018 to December 2018. 3. The laboratory director and testing personnel confirmed on February 6, 2019, that the laboratory did not have these PRPTP testing records. 4. This deficiency was cited on February 14, 2017.
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 procedures manual, hematology quality control records review

	from January 2017 to December 2018 and laboratory director and testing personnel interview at 10:55 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 Coulter AcT 5 Diff system. The findings include: 1. The laboratory uses a Coulter AcT 5 Diff 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 Coulter AcT 5 Diff system since March 21, 2018. 3. The laboratory director and testing personnel stated on February 6, 2019, that the laboratory did not perform at least 6 months the calibration verification procedures for hematology tests by the Coulter AcT 5 Diff system. 4. This deficiency was cited on February 14, 2017.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on procedures manual, hematology quality control records review from January 2, 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at 10:48 AM, it was determined that the laboratory failed to evaluate the quality control results for the hematology tests processed by the Coulter AcT 5 Diff system. The finding include: 1. The laboratory uses a Coulter AcT 5 Diff system to perform hematology patients samples tests. 2. The laboratory establishes to evaluate Levy Jennings graphs the quality control results each month. 3. Review of hematology quality control records from January 2017 to December 2018, showed that the laboratory performed quality control procedures from February 2017 to December 2017, however, did not evaluate in Levy Jennings graphs the quality control results. 4. The laboratory director and testing personnel stated on February 6, 2019, that the laboratory performed the quality control but not evaluate in Levy Jennings graphs the quality control results those months. 5. The laboratory performed and reported approximately 1,515 hematology patient's samples from July 2018 to December 2018.
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 from January 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 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 at least every 6 months the calibration verification procedures for the hematology tests processed by the Coulter AcT 5 Diff system. b. to evaluate the quality control results for the hematology tests processed by the Coulter AcT 5 Diff system.
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 from February 2017 to December 2018, hematology quality control records review and laboratory director and testing personnel interview on February 6, 2019 at 11:55 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, D2016, D2128, D3031 and D3037. 2. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D6092, D6093 and D6094.
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 from February 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at 10:22 AM, it was determined that the laboratory director did not take nor document a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2017 to December 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Hematology Cell Identification tests in March 2017 (PRPTP first testing event). No remedial actions were taken. 3. The laboratory

	director and testing personnel confirmed on February 6, 2019, that the laboratory did not take corrective actions on this testing events. Refer to D2128.
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 procedures manual, hematology quality control records review from January 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 at 11:55 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5439 and D5469.
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 from January 2017 to December 2018 and laboratory director and testing personnel interview on February 6, 2019 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. Refer to D5791.