

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0960064	(X3) Date Survey Completed 04/06/2018
Name of Provider or Supplier Lab Clin Y Bacteriologico Del Mar	Street Address, City, State Carr 110 Barrio Aguacate, San Antonio, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of routine chemistry statistical parameters from years 2016 to 2018, review of patient data log from years 2017 to 2018 and laboratory director interview on April 6, 2018 at 11:30 AM, it was found that the laboratory did not evaluate nor define the statistical values of the commercial control material used by the Vitros 250 instrument. The findings include: 1. The laboratory processed the following tests by the Vitros 250 routine chemistry system: Basic Metabolic Panel (BMP), Lipid Panel and Comprehensive Metabolic Panel (CMP). 2. The laboratory uses Verify I and Verify II as normal and abnormal control materials, respectively for Vitros 250 system. 3. Review of routine chemistry quality control records from January 2017 to December 2017, the laboratory did not have nor document the routine chemistry control materials results in any statistical data (Levy-Jennings, control value mean and limits) every day of testing since year 2017. 4. The patient data log for year 2017 showed that the laboratory processed and reported nine (9) Comprehensive Metabolic</p>

	<p>Panel (CMP) patient's samples in the following days: Date Tests # samples 2/17/17 CMP 1 2/23/17 CMP 1 6/20/17 CMP 1 6/21/17 CMP 1 6/22/17 CMP 1 6/27/17 CMP 1 7/20/17 CMP 1 7/28/17 CMP 1 8/29/17 CMP 1 5. The laboratory director confirmed on April 6, 2018 that the laboratory did not have nor document the routine chemistry control materials results in any statistical data (Levy-Jennings, control value mean and limits) every day of testing since year 2017.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review in 2016-2018 and laboratory director interview on April 6, 2016 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 did not evaluate nor define the statistical values of the commercial control material used by the Vitros 250 instrument. Refer to D5469.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on routine chemistry quality control records review from April 2016 to March 2018 and laboratory director interview at 11:30 AM on April 6, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5469.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review in 2016-2018 and laboratory director interview at 11:30 AM on April 6, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.</p>