

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0678283	<b>(X3) Date Survey Completed</b> 02/06/2020
<b>Name of Provider or Supplier</b> Laboratono Clinico San Martin	<b>Street Address, City, State</b> De Diego 403, San Juan, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of validation records of the Selectra Pro system and laboratory director interview at 11:40 AM on February 6, 2020, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,042 out of 1,042 patient's routine chemistry tests results during the year 2019 (cholesterol, glucose, triglycerides and HDL-Cholesterol). The findings include: 1. The laboratory validated the Selectra Pro system on May 31, 2018 for routine chemistry tests (cholesterol, glucose, triglycerides and HDL-Cholesterol). 2. At 11:40 AM on February 6, 2020, the validation records of the Selectra Pro system showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,042 out of 1,042 patient's results for routine chemistry tests (cholesterol, glucose, triglycerides and HDL-Cholesterol) during the year 2019. 3. The laboratory director confirmed at 11:40 AM on February 6, 2020, that the laboratory did not verify that the manufacturer's reference intervals (normal values) for those tests before reporting patient's results during the year 2019. 4. The laboratory processed and reported 1,042 out of 1,042 routine chemistry tests during the year 2019.</p>

**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 review of validation records of the Selectra Pro system and laboratory director interview at 11:40 AM on February 6, 2020, it was determined that the laboratory director failed to comply with the analytic system requirements for the routine chemistry tests. Refer to D5421 (The laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,042 out of 1,042 patient's routine chemistry tests results during the year 2019).