

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1018027	<b>(X3) Date Survey Completed</b>  06/07/2018
<b>Name of Provider or Supplier</b>  Lab Clinico Santa Cruz	<b>Street Address, City, State</b>  Carr 181 Ramal 852 Km 1 Hm 8 Quebrada Grande, Trujillo Alto, 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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on Cobas c501 Module maintenance log information records, Cobas c501 module maintenance log records (years 2017 to 2018) review and technical consultant interview on June 7, 2018 at 10:50 AM, it was determined that the laboratory failed to follow manufacturer's instruction for preventive maintenance when the laboratory processed for the following tests by the Cobas c501 system from August 21, 2017 to June 6, 2018: 3,600 comprehensive metabolic panel (CMP) , 3,316 lipid profile and 2,188 glycohemoglobin). The findings include: 1. On June 7, 2018 at 10:50 AM, the Cobas c501 Module maintenance log information record showed that the Cobas c501 Module manufacturer instructed the laboratory to perform the following preventive maintenance: a. Replace the photometer lamp when the photometer reading at 340nm is &gt; 14,000 or every 6 months whichever comes first. b. Replace every 2 months the reaction cells. c. Replace every 6 months the ISE Ref. Cartridge. 2. The Cobas c501 module maintenance log records showed that the laboratory did not replace the photometer lamp, the reaction cells nor the ISE Ref. Cartridge from August 21, 2017 to June 6, 2018. 3. The technical consultant confirmed on June 7, 2018 at 10:50 AM, that the laboratory did not perform the preventive maintenance of the Cobas c501 manufacturer instructions due to the laboratory followed the instructions for the preventive antennae from the Cobas c501 module technician. 4. From August 21, 2017 to June 6, 2018, the laboratory processed for the following tests by the Cobas c501 system: 3,600 CMP, 3,316 lipid profile and 2,188 glycohemoglobin.</p>

**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 Cobas c501 Module maintenance log information records, Cobas c501 module maintenance log records (years 2017 to 2018) review and technical consultant interview on June 7, 2018 at 10:50 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system for the routine chemistry tests results. The finding includes: 1. The laboratory director failed to ensure that the laboratory follow manufacturer's instruction for preventive maintenance when it processed for the following tests by the Cobas c501 system from August 21, 2017 to June 6, 2018: 3,600 CMP, 3,316 lipid profile and 2,188 glycohemoglobin). Refer to D 5429.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on Cobas c501 Module maintenance log information records, Cobas c501 module maintenance log records (years 2017 to 2018) review and technical consultant interview on June 7, 2018 at 10:50 AM, it was determined that the technical consultant failed to ensure that the laboratory follow manufacturer's instruction for preventive maintenance when it processed for the following tests by the Cobas c501 system from August 21, 2017 to June 6, 2018: 3,600 CMP, 3,316 lipid profile and 2,188 glycohemoglobin. Refer to D 5429.