

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658042	<b>(X3) Date Survey Completed</b>  09/12/2018
<b>Name of Provider or Supplier</b>  Lab Clinico Bacteriologico Los Angeles	<b>Street Address, City, State</b>  Calle Lope Flores B24 Urb Paradise, Caguas, 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual, hematology quality control records review in years 2017-2018 and laboratory general supervisor interview on September 12, 2018 at 11:00 AM, it was determined that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). The findings include: 1. The laboratory uses CoaData system to perform coagulation patient's samples tests. (PT-PTT) (Prothrombin Time and Partial Tromboplastin Time) 2. The laboratory placed in routine use the following thromboplastin reagent (STA-NeoplastineCl Plus, Lot. 251722, Exp. 2/28/19) on September 2018. 3. The laboratory did not establish a normal population prothrombn (PT) mean for each new lot number. 4. The laboratory general supervisor stated that unknown is the former laboratory PT mean that the system used. 5. The laboratory processed and reported two (2) patient's samples on September 5, 2018. (ID # 4415769 and 4417564).</p>
<b>D5405</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p>

This STANDARD is not met as evidenced by:  
 Based on manufacturer's instructions, syphilis serology quality control review in years 2017-2018 and laboratory general supervisor interview at 10:00 AM on September 12, 2018, it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Detector-rpr method. The findings include: 1. The The laboratory uses Detector-rpr method to perform RPR (rapid plasma reagin) syphilis serology patient's samples tests. 2. The manufacturer's instruction establishes that three levels of control material ( non reactive, minimal to moderate and reactive) must be included each day of testing. 3. Review of quality control syphilis serology from January 2017 to September 2018, showed that the laboratory did not include the three levels of control material in the following days: Date #'s samples 4/11/18 27 4/12/18 1 4/13/18 1 7/26 /18 1 4. The laboratory processed and reported thirty (30) patient samples for RPR (rapid plasma reagin) those days. 5. The laboratory general supervisor stated on September 12, 2018 that the laboratory did not include the three levels of control material those days.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
 Based on manufacturer's instructions, syphilis serology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:00 AM on September 12, 2018, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by Detector-rpr method. The findings include: 1. The laboratory uses Detector-rpr method to perform RPR (rapid plasma reagin) syphilis serology patient's samples tests. 2. The manufacturer's requires that the laboratory must perform the needle calibration, verify the rotator rpm and monitor the room temperature in the laboratory. 3. Review of syphilis serology records January 2017 to September 2018, showed that the laboratory did not document nor verify the needle calibration, rotator rpm nor the room temperature monitoring in the RPR (Rapid plasma reagin) testing area in the following days: Date #samples 4/11/18 27 4/12/18 1 4/13/18 1 7/26/18 1 4. The laboratory processed and reported thirty (30) RPR (Rapid plasma reagin) patient's samples tests those days. 5. The laboratory general supervisor stated on September 12, 2018 that the laboratory did not document nor verify the needle calibration, rotator rpm nor the room temperature monitoring in the RPR (Rapid plasma reagin) testing area those days.

**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 hematology quality control records review in years 2017-2018 and laboratory general supervisor interview at 11:00 AM on September 12, 2018, it was determined that the laboratory failed to verify the criteria for acceptability of the hematology control materials used by the CoaData system. The findings include: 1. The laboratory uses a CoaData system to perform PT and PTT patient's samples tests. 2. Review of hematology quality control records from January 2017 to September 2018, showed that the laboratory did not evaluate the coagulations studies controls (Lot number Coag control N252096, Exp. 2/2019) prior to use it on September 5, 2018.

**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 manufacturer's instructions, hematology and syphilis serology quality controls records review in years 2017-2018 and laboratory general supervisor interview at 11:00 AM on September 12, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401. 2. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Detector-rpr method. Refer to D5405 and D5411. 3. The laboratory failed to verify the criteria for acceptability of the hematology control materials used by the CoaData system. Refer to D5469.

**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 manufacturer's instructions, hematology and syphilis serology quality control records review in years 2017-2018 and laboratory general supervisor interview at 11:00 AM on September 12, 2018, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory

failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401. 2. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for RPR (Rapid plasma reagin) by Detector-rpr method. Refer to D5405 and D5411. 3. The laboratory failed to verify the criteria for acceptability of the hematology control materials used by the CoaData system. Refer to D5469.