

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0988584	<b>(X3) Date Survey Completed</b>  05/17/2024
<b>Name of Provider or Supplier</b>  Lab Clinico Colon # 3	<b>Street Address, City, State</b>  Rosado Medical Building Suite 201 203, Humacao, 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>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> <p>This STANDARD is not met as evidenced by: Based on Rapid Reagin Plasma (RPR) ASI manufacturer's instruction, testing records (year 2023), laboratory syphilis serology procedures manual review and interview with the laboratory technical consultant on May 17, 2024 at 11:24 AM, it was determined that the laboratory failed to follow, both the manufacturer's instructions and its own written procedures, when one (1) patient specimen were processed and reported for RPR quantitative tests on April 21, 2023. The findings include: a. The laboratory performed the RPR quantitative tests by ASI method. b. Both, the ASI manufacturer's instructions, as well as the procedures manual, instructed that every reactive patient the laboratory has to perform and document an serial dilution until 1:16. If the patient serum still reactive the laboratory has to perform and document an serial patient's serum dilution until the end ponit. c. Review of the RPR quantitative patient's testing records (year 2023), showed on April 21, 2023; that the laboratory performed an a serial dilution for the patient ID 427431 until 1:64. d. The laboratory did not continue to test serial dilution until the end point. e. The laboratory technical consultant confirmed on May 17, 2024 at 11:35 AM; that the laboratory failed to follow the manufacturer's instructions and procedure manual when not performed the serial dilutions until end point.</p>
<b>D6040</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p>

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on Rapid Reagin Plasma (RPR) ASI manufacturer's instruction, testing records (year 2023), laboratory syphilis serology procedures manual review and interview with the laboratory technical consultant on May 17, 2024 at 12:08 PM, it was determined that the technical consultant failed to verify the test procedures performed and the establishment procedure manual when the laboratory processed and reported one (1) patient specimen 1:64 (reactive) and did not continue to test serial dilutions until the end point. Refer to D5405.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Rapid Reagin Plasma (RPR) manufacturer's instructions, RPR procedure manual, RPR worksheet records and laboratory technical consultant interview on May 17, 2024 at 12:10 PM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the laboratory follow the manufacture's instructions, procedure manual established for the serial dilutions for RPR on April 21, 2023. Refer D5405