

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>40D0933157</p>	<p><b>(X3) Date Survey Completed</b></p> <p>05/17/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>Laboratorio Clinico Plaza Del Norte</p>	<p><b>Street Address, City, State</b></p> <p>Carr # 2 Km 82, Marginal, Bo Carrizalez, Hatillo, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D5405</b></p>	<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 RPR ( Rapid plasma reagent -AIM) manufacturer's instructions and RPR testing record review from January 5, 2023 to May 14, 2024 and interview with the laboratory director on May 17, 2024 at 9:30 A.M., it was determined that the laboratory failed to follow the manufacturer's instruction when 111 out of 111 patients specimens were tested and reported for RPR test from January 2023 to May 2024. The findings include: 1. The laboratory perform syphilis serology test by AIM- Rapid plasma reagent. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 20 to 30 C. ( review on May 17, 2024 at 9:30 A.M. ) 3. On May 17, 2014 at 9:35 A.M. review of the RPR testing records showed that the laboratory failed to follow the room temperature establishes when patient's specimens were tested for syphilis serology from January 2023 to May 2024. 4. The RPR testing records showed that the laboratory documented a temperature 31 C since January 5, 2023 when it processed the patients specimens for RPR test. ( review on May 17, 2024 at 9:35 A.M. ) 5. The laboratory processed and reported 111 out of 111 patient samples for RPR test from Janary 5, 2023 to May 14, 2024. 6. The laboratory director confirmed on May 17, 2024 at 9:45 A.M., that the laboratory documented a temperature of 31 C each day of testing.</p>
<p><b>D6020</b></p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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 syphilis serology manufacturers instructions, quality control records review from January 2023 to May 2024 and interview with the laboratory director on May 17, 2024 at 11:30 A.M., it was determined that the laboratory director (testing personnel) failed to follow the manufacturer's instruction when 111 out of 111 patients specimens were tested and reported for RPR test. Refer to D5405.