

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2103412	<b>(X3) Date Survey Completed</b>  02/19/2021
<b>Name of Provider or Supplier</b>  Laboratorio Neoclinico	<b>Street Address, City, State</b>  Carr, Pr -2, Km 18, Hm 9, Comunidad Macun, Toa Baja, 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>D2072</b>	<p><b>SYPHILIS SEROLOGY</b> CFR(s): 493.835(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to December 2020 and laboratory general supervisor interview on February 19, 2021 at 9:35 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in syphilis serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed since February 2019 to December 2020. 2. Review of PRPTP testing records, showed that the laboratory obtained unsatisfactory results of 60 percent in syphilis serology (qualitative) and syphilis serology (quantitative) tests in September 2020 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on February 19, 2021, that the laboratory did not take corrective actions on this testing event.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <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</p>

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to December 2020 and laboratory general supervisor interview on February 19, 2021 at 9:35 AM, it was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained unsatisfactory results.

The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2019 to December 2020. 2. Review of PRPTP testing records, showed that the laboratory obtained unsatisfactory results of 60 percent in syphilis serology (qualitative) and syphilis serology (quantitative) tests in September 2020 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on February 19, 2021, that the laboratory did not take corrective actions on this testing event. Refer to D2072.