

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0899990	<b>(X3) Date Survey Completed</b>  07/11/2024
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Y Bacteriologico Santiago	<b>Street Address, City, State</b>  Carretera 111 Km 51 Hm 7 Bo Caguana, Utuado, 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>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LABORATORIO CLINICO Y BACTERIOLOGICO SANTIAGO on July 11, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on July 11, 2024.
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on human chorionic gonadotropin (hCG) quality control records review (years 2023-2024), patient's test worksheets records review and laboratory director interview on July 11, 2024 at 10:45 AM, it was determined that the laboratory failed to include an external negative and positive control material each day of testing when performed and reported 14 out of 32 hCG patient's samples from December 4, 2023 to June 13, 2024. The findings include : 1. The laboratory performed hCG patient's test by Alere one step method. (Reviewed on July 11, 2024 at 10:45 AM.) 2. The hCG quality control and patient's test worksheets records were reviewed from January 2023 to June 13, 2024. (Reviewed on July 11, 2024 at 10:50 AM.) 3. The hCG quality control record showed that the laboratory did not include an external negative and positive control material, each testing day, from December 4, 2023, to June 13, 2024. The laboratory only documented the internal procedure control with each patient. (Reviewed on July 11, 2024 at 10:55 AM.) 4. The laboratory director confirmed on July 11, 2024 at 11:00 AM., that the laboratory failed to include a negative and</p>

positive control material each day of testing when performed hCG test. B. Based on Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review (year 2023-2024) and laboratory director interview on July 11, 2024 at 11:05 AM, it was determined that the laboratory failed to include an external negative and positive control material each day of Mycoplasma pneumoniae IgM patient testing, when 56 out of 99 patients were processed and reported from November 30, 2023 to April 29, 2024. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. (Reviewed on July 11, 2024 at 11:05 AM.) 2. The Mycoplasma pneumoniae IgM quality control and patient's test worksheets reports were reviewed from November 30, 2023 to July 9, 2024. (Reviewed on July 11, 2024 at 11:10 AM.) 3. The Mycoplasma pneumoniae IgM quality control and patient test worksheet records on July 11, 2024 at 11:10 AM, showed that the laboratory did not include any control material each day of patient testing from November 30, 2023 to April 29, 2024, when 56 out of 99 patients were processed and reported for Mycoplasma pneumoniae IgM testing. 4. The laboratory director confirmed on July 11, 2024 at 11:20 AM, that the laboratory failed to include a negative and positive control material each day of patient testing for Mycoplasma pneumoniae IgM.

**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 hCG and Mycoplasma pneumoniae IgM test quality control, patient test worksheet records review and laboratory director interview on July 11, 2024 at 1:00 P. M., it was determined that the laboratory director did not make sure to include a positive and a negative control material each day of patient testing for hCG and Mycoplasma pneumonia IgM tests. Refer to D5449.