

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0677932	<b>(X3) Date Survey Completed</b>  07/17/2024
<b>Name of Provider or Supplier</b>  Lab Clinico Caribe	<b>Street Address, City, State</b>  Gautier Benitez #8, Cidra, 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 CARIBE on July 17, 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 17, 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 endocrinology quality control records review ( years 2023-2024 ), patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 17, 2024 at 10:45 AM, it was determined that the laboratory failed to include a negative and positive control material each day of testing when reported and performed hCG (Human chorionic gonadotropin) tests 4 out of 158 patient's samples in 3 out 73 of days (year 2023) and 15 out of 80 patient's samples in 6 out 45 of days (year 2024) by Aime One Step Method by Germaine. The findings include : 1. The laboratory performed hCG ( human chorionic gonadotropin) by Aim One Step method. Review on July 17, 2024 at 10:45 AM 2. The endocrinology quality control logs and patient's reports worksheets were reviewed from January 2, 2023 to July 16, 2024. Review on July 17, 2024 at 10:55 AM. 3. The endocrinology quality control logs and patient's reports worksheets records showed that the laboratory did not include a negative and positive control material each day of testing from January 2, 2023 to July 16, 2024, when peformed and reported 20</p>

patient's samples in the following days: (reviewed on July 17, 2024 at 11:05 AM) Date hCG patient's samples 1/25/2023 2 3/20/2023 1 5/9/2023 1 1/24/2024 3 2/1/2024 2 2/6/2024 1 2/20/2024 5 2/23/2024 3 7/10/2024 1 4. The laboratory general supervisor confirmed on July 17, 2024 at 11:10 AM, that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test. B. Based on general immunology quality control records review ( years 2023-2024 ), patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 17, 2024 at 9:40 AM, it was determined that the laboratory failed to include a negative and positive control material each day of testing when reported and performed Mycoplasma Ig M tests 17 out of 406 patient's samples in 5 out 110 of days (year 2024) by Immunocard by Meridian. The findings include : 1. The laboratory performed Mycoplasma Ig M by Immunocard Meridian method. Review on July 17, 2024 at 9:40 AM 2. The general immunology quality control logs and patient's reports worksheets were reviewed from January 2, 2023 to July 16, 2024. Review on July 17, 2024 at 9:55 AM. 3. The general immunology quality control logs and patient's reports worksheets records showed that the laboratory did not include a negative and positive control material each day of testing from January 2, 2023 to July 16, 2024 when performed and reported 17 patient's samples in the following days: (reviewed on July 17, 2024 at 10:05 AM) Date Mycoplasma IgM patient's samples 4/1/2024 4 4/2/2024 1 4/3/2024 7 4/22/2024 3 5/29/2024 2 4. The laboratory general supervisor confirmed on July 17, 2024 at 10:10 AM, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma Ig M patient's tests.

**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 endocrinology and general immunology quality control (years 2023-2024) patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 17, 2024 at 11:25 AM, it was determined that the director failed to ensure the compliance with the quality control program when reported and performed hCG (Human chorionic gonadotropin) tests 4 out of 158 patient's samples in 3 out 73 of days (year 2023) and 15 out of 80 patient's samples in 6 out 45 of days (year 2024) by Aime One Step Method by Germaine and Mycoplasma Ig M tests 17 out of 406 patient's samples in 5 out 110 of days (year 2024) by Immunocard by Meridian. Refer to D5449.