

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D1084511</p>	<p>(X3) Date Survey Completed</p> <p>10/24/2024</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Clinico Pastillo</p>	<p>Street Address, City, State</p> <p>Carr Pr-1 Km 113 Hm 6 Bo Cintrona, Juana Diaz, 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>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Pastillo on October 24, 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 October 24, 2024.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES 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: Based on Human chorionic gonadotropin (hCG) test quality control records, patient test worksheet records review and interview with the laboratory supervisor on October 24, 2024 at 11:20 A.M., it was determined that the laboratory did not include an external positive and negative control material each day of hCG patient testing. From January 30, 2024 to September 16, 2024; when 62 out of 84 patients were processed and reported. The findings include: 1. Review of hCG quality control records and patient test worksheet records on October 24, 2024 at 11:00 A.M., showed that the laboratory did not include the external positive and negative control material each day of patient testing from January 30, 2024 to September 16, 2024. 2. The laboratory supervisor confirmed on October 24, 2024 at 11:20 A.M., that the laboratory failed to include a negative and positive external control material each day of patient testing. From January 30, 2024 to September 16, 2024; when 62 out of 84 patients were processed and reported.</p>

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 Human chorionic gonadotropin (hCG) quality control and patient test worksheet records review, and laboratory supervisor interview on October 24, 2024 at 11:20 AM, it was determined that the laboratory director did not ensure to include a positive and a negative control material each day of patient testing for hCG tests. Refer to D5449.