

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658023	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Laboratorio Clinico Plaza	Street Address, City, State Ave Aguas Buenas Bloque 10-2, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5449	<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 Pregnancy test quality control records (year 2021 to 2022) review, pregnancy worksheet records review and interview with the laboratory director and laboratory supervisor on April 13, 2023 at 11:45 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control materials when 16 out of 16 patients specimens were tested and reported for of pregnancy qualitative test from May 13, 2022 to December 19, 2022. The findings include: 1. The laboratory use the Aim Step method to perform the Pregnancy qualitative tests. 2. On April 13, 2023 at 11:15 AM, the pregnancy control records and worksheet records were reviewed years 2021 to 2022 3. On April 13, 2023 at 11:20 AM the pregnancy quality control records showed that the laboratory did not run an external positive and negative control meterial when 16 out of 16 patients specimens was tested and reported for pregnancy qualitative test from May 13, 2022 to December 19, 2022 4. The laboratory director and laboratory supervisor confirmed on April 13, 2023 at 11:45 AM, that the laboratory did not run an external positive and negative control material from May 13, 2022 to December 19, 2022 when 16 out of 16 patient's were processed and reported for pregnancy qualitative test</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

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 Pregnancy test quality control records (year 2021 to 2022) review, and interview with the laboratory director and laboratory supervisor, on April 13, 2023 at 11:45 AM; it was determined that the laboratory director failed to maintain the quality control procedures for the Pregnancy qualitative test. Refer to D 5449.