

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0856733	(X3) Date Survey Completed 02/22/2022
Name of Provider or Supplier Laboratorio Clinico Migrant San German	Street Address, City, State Ave Universidad Interamericana 158, Bo Pueblo, San German, 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 endocrinology quality control records review (year 2021) and interview with the laboratory supervisor it was determined that the laboratory failed to include a negative and positive external control material when performed hCG (Human Chorionic Gonadotropin) tests. The finding include : a. Endocrinology quality control logs were reviewed on February 22, 2022 at 2:23 PM from January to November 2021. b. Review of records showed that the laboratory did not include a positive nor a negative external control material when patient's test were performed from January 5, 2021 to November 24, 2021. The laboratory processed and reported 11 out of 12 patient. c. The laboratory supervisor on February 22, 2022 at 2:23 PM, stated that the laboratory only run external control with each new lot kit.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <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.</p>

This STANDARD is not met as evidenced by:

Based on endocrinology quality control records review (years 2021) and laboratory general supervisor interview it was found that the laboratory director did not assure that quality control procedures were followed. The findings include: 1. On February 22, 2022 at 2:25 PM the laboratory supervisor confirmed that the laboratory did not run an external positive and negative control each day of patient testing. Refer to D5449.