

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658222	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Quest Diagnostics Laboratorios De Analisis Clinico	Street Address, City, State H 44 Marginal St Santa Rita, Vega Alta, 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, patient log, procedure manual review (year 2017 to 2018) and interview with the laboratory supervisor at 10:30 AM on October 30, 2018 , it was determined that the laboratory failed to include a negative and positive control material when performed serum hCG (Human Chorionic Gonadotropin) tests. The finding include : a. Endocrinology quality control logs were reviewed from January 207 to October 8, 2018. b. Review of records showed that the laboratory performed hCG (Human Chorionic Gonadotropin) 5 days in year 2017 and 11 days in 2018. c. The laboratory did not include an external control material (negative nor positive) in 2 out of 5 days in year 2017: 3/20/2017 patient identification # 24293127 and on 5/8/2017 patient identification # 24654136. d. The laboratory did not include an external control material (negative nor positive) in 11 out of 11 days in year 2018: 2/6/2018 -patient identification # 25436434 2/7/2018 - patient identification # 25439916 4/5/2018 - patient identification # 25566470 4/14/2018 - patient identification # 25590737 5/29/2018 - patient identification # 25701068 6/11 /2018 - patient identification # 25732102 7/24/2018 - patient identification #25835390 8/17/2018 - patient identification # 25897281 8/30/2018 - patient identification # 25935240 9/1/2018 - patient identification # 25987734 10/8/2018 - patient identification # 25041939 e. Review of the procedure manual (page 4) under: Frequency, showed the following " External controls (Positive and Negative) will be analyzed and documented each day of use before patient samples are analyzed" c. The</p>

supervisor stated that the laboratory verified and documented the procedural controls with each patient, but he don't know why the rule included in the procedure manual was not followed.

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 quality control records review and interview with the laboratory director on October 30, 2018 at 11:40 AM, it was determined that the laboratory director did not assure that external control material were included each day of testing for hCG test. Refer to D 5449.