

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0890119	(X3) Date Survey Completed 07/05/2018
Name of Provider or Supplier Dr Guerra Clinic	Street Address, City, State 38-27 98th Street, 2nd Floor, Corona, NY	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of a Individualized Quality Control Plan (IQCP) procedure and an interview with the laboratory testing person, the laboratory failed to have a complete IQCP for Bacteriology and Endocrinology testing. Findings Include: It was confirmed with the laboratory testing person on July 5, 2018 at approximately 2:00 PM, that the laboratory failed to have all three components for the IQCP procedures, which consists of Quality Control Procedure (QCP), Quality Assessment Procedure (QAP) and Risk Assessment Procedure (RA) for the Quidel, Quick Vues Kits for Pregnancy and Chlamydia testing.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a lack of procedures and an interview with the laboratory testing person, the director failed to have written procedures for their IQCP. Refer to D5445