

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0150007	(X3) Date Survey Completed 01/29/2019
Name of Provider or Supplier Kew Gardens Hills Pediatric	Street Address, City, State 141-49 70th Road, Flushing, 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 the surveyor's review of the laboratory's policies and procedures and an interview with the office manager, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individualized Quality Control Plan (IQCP) for testing Group A Strep and for performing throat culture testing using Select Strep Agar and Bacitracin disk. Findings Include: The office manager confirmed during the January 29, 2019 onsite survey at approximately 1:30 pm that the laboratory failed to establish a Risk Assessment plan to identify and evaluate potential failures and sources of error for testing Group A Strep with Bacitracin disk, to include the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel.</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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy/procedure manual and an interview with the office Manger, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D5445

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the the office manager, the laboratory director failed to ensure that appropriate training was documented for 2 of 2 new testing personnel who recently began patient testing for the moderately complex test for throat cultures.