

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0994451	(X3) Date Survey Completed 03/22/2018
Name of Provider or Supplier Kakossian Medical Woman Care Pc	Street Address, City, State 1180 Brighton Beach Avenue, First Floor, Brooklyn, 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 Quality Control Plan (QCP) and Quality Assessment (QA) procedures and an interview with the testing person, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individualized Quality Control Plan (IQCP) for the Affirm VPIII Microbial Identification Test. Findings: The testing person confirmed during the March 22, 2018 onsite survey, at approximately 4:00 PM, that the laboratory director failed to establish a Risk Assessment (RA) plan to include all phases of bacteriology, mycology and parasitology testing using the Affirm VPIII microbial identification system, to include potential sources of error for the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel.</p>
D6020	<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</p>

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 the quality control program is 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 QC records and confirmed in an interview with the testing person, the laboratory director failed to ensure that the QC program for bacteriology, mycology and parasitology testing was maintained to assure quality of laboratory services. Refer to: D5445