

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2079846	(X3) Date Survey Completed 11/30/2021
Name of Provider or Supplier Khoury Medical Care Pc	Street Address, City, State 1184 Brighton Beach Avenue, 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 Quality Control Plan (IQCP), QC records for the Affirm VIII test system and an interview with the technical consultant, the laboratory failed to established a Quality Control Plan (QCP) section of the IQCP for the Affirm VIII and perform and investigation to identify the testing system failure under Risk Assessment section of the IQCP. FINDINGS: 1. The technical consultant confirmed on November 30, 2021 at approximately 1:30 PM the surveyor's findings that the laboratory failed to establish a QCP to include the number of controls, the type of controls and the frequency controls are performed, as part of a complete IQCP. a. The QCP section of the laboratory's established IQCP states, "Monitor QC and precision of test performance and must include number of QC, type of QC, frequency of QC." The QCP failed to define the number of controls, frequency of controls and type of controls. 2. The BD Affirm VPIII Microbial Identification Test includes two internal controls on each PAC: a Positive Control bead and a Negative Control bead. These control beads are tested simultaneously with each patient specimen, ensuring the proper performance of PAC, Reagent Cassette (RC) and Processor. Each new lot and/or shipment of PAC test cassettes must be tested with a commercially prepared Trivalent swab of Candida albicans, Trichomonas and Gardnerella species to assure</p>

adequate sample lysis. a. Surveyor reviewed the following QC records (internal & external) for 2021: Date performed/Kit lot # & expiration date/Control lot # & expiration date/internal & external results 2/15/21 #7036104 expires 5/21/21-Negative #20346781 expires 6/19/22 results- negative 2/15/21 #7036104 expires 5/21/21-Positive #20346781 expires 6/19/22 results- positive 6/23/21 #7739247 expires 3/5/22-Negative #2004568 expires 7/3/22 results - negative 6/23/21 #7739247 expires 3/5/22-Positive #2004568 expires 7/3/22 results - positive 10/9/21 #7781482 expires 5/3/22-Negative #20375484 expires 9/1/22 results -negative 5/23/21 #7739247 expires 3/5/22-Positive #2004568 expires 7/3/22 results -positive 3. The laboratory director failed to establish a Risk Assessment (RA) plan to include all phases of bacteriology, mycology and parasitology testing using the Affirm VIII microbial identification system, to include potential sources of error for the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel.