

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403189	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Ogi - Edina	Street Address, City, State 6405 France Ave S #W400, Edina, MN	
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
D5461	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control on new test kits prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, and Parasitology testing as confirmed by Testing Personnel 8 (TP8) during a tour of the laboratory at 1:10 p.m. on 09/04/19. 2. A BD Affirm Microprobe processor was observed as present and available for use during the tour. The laboratory performed Trichomonas, Gardnerella, and Candida testing using this processor. 3. Quality control (QC) testing was required with every new test kit as established in the BD Affirm VP III Microbial Identification Test procedure found in the un-named procedure manual. 4. In June 2018 through August 2018, the laboratory failed to perform QC on four of eight new test kits prior to testing patient (Pt) samples which potentially affected 7 patients. See below. Lot Pt testing date Pts QC date 8072819 6/29/18 3 7/2/18 6/30/19 1 7/2/18 8075689 7/17/18 1 7/18/18 8108857 7/30/18 1 7/31/18 8072822 8/6/18 1 8/7/18 5. In an interview at 3:30 p.m. on 09/04/19, TP8 confirmed the above finding.</p>