

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0400928	(X3) Date Survey Completed 12/30/2020
Name of Provider or Supplier Obgyn West Eden Prairie	Street Address, City, State 800 Prairie Center Dr Ste 130, Eden Prairie, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</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 and document required monthly maintenance on 1 of 2 analyzers in use in 2020.. Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the Laboratory Manager (LM) during a tour of the laboratory at 9:20 a.m. on 12/30/20. 2. A Cepheid GeneXpert analyzer was observed as present and available for use during the tour of the laboratory. The LM indicated Chlamydia and Neisseria Gonorrhoea testing on the GeneXpert was implemented on 04/24/20. 3. Manufacturer requirements for monthly maintenance of the GeneXpert analyzer were established in the Xpert CT/NG Procedure located in the Cepheid Assay Binder manual and indicated on the laboratory's Maintenance Log. 4. Documentation of monthly maintenance was not found for 5 of 9 months reviewed in the following timeframe; April 2020 through December 2020. See below. Months missed 2020 May June July August October 5. In an interview at 11:45 a.m. on 12/30 /20, the LM confirmed the above finding.</p>