

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0665003	<b>(X3) Date Survey Completed</b>  03/19/2024
<b>Name of Provider or Supplier</b>  Obgyn West Minnetonka	<b>Street Address, City, State</b>  14001 Ridgedale Dr, Minnetonka, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The OBGYN West Minnetonka laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on March 19, 2024. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1413 Technical consultant responsibilities .
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a performance verification (PV) for two of three non-waived Microbiology tests implemented by the laboratory in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:35 p. m. on 03/19/24. 2. A Cepheid GeneXpert XVI test system was observed as present and available for use during the tour. The laboratory implemented this test system on 05/12/23 using the following tests: Xpert Xpress MVP - Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis Xpert GBS - Group B Streptococcus Xpert CT/NG - Chlamydia trachomatis and Neisseria gonorrhoeae 3. PV documentation for GBS and CT/NG testing on the GeneXpert test system was not</p>

found during review of laboratory records. The laboratory was unable to provide the PV documentation for these tests upon request. 4. Test performance verification was required when a test system was installed or replaced with the same or different model as established in the Evaluation of Test Methods procedure found in the General Laboratory Policy and Procedure Manual. 5. In an interview at 4:15 p.m. on 03/19/24, the TC confirmed the above finding. 6. In an interview at 4:40 p.m. on 03/19/24, the TC indicated 868 patients received testing since implementation on 05/12/23 through date of survey, 03/19/24. See below Test Number of patients tested GBS 148 CT/NG 720 .

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure one of five testing personnel (TP) was assessed semi-annually and annually through testing previously analyzed specimens, blind samples, or proficiency testing samples for three of four tests performed in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology and Diagnostic Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:35 p.m. on 03/19/24. 2. A Cepheid GeneXpert XVI test system was observed as present and available for use during the tour. The laboratory performed the following tests on this test system in 2023: Xpert Xpress MVP - Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis Xpert GBS - Group B Streptococcus Xpert CT/NG - Chlamydia trachomatis and Neisseria gonorrhoeae 3. Assessment of test performance using previously analyzed specimens, internal blind samples, or external proficiency samples was required semi-annually for new TP and annually for all TP as established in the Staff Orientation, Training and Competency procedure found in the General Laboratory Policy and Procedure Manual. 4. Blind sample competency assessments were not documented as completed on TP6's 2023 semi-annual and annual competency evaluation forms for the above moderate complexity tests. 5. The laboratory was unable to provide the missing blind sample evaluation documentation upon request. 6. In an interview at 2:25 p.m. on 03/19/24, the TC confirmed the above finding. .