

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0400928	(X3) Date Survey Completed 05/01/2024
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
D0000	The OBGYN West Eden Prairie 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 May 1, 2024. The following standard-level deficiency was cited: 493.1413 Technical consultant responsibilities .
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> <p>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 four testing personnel (TP) in 2022 and one of five TP in 2023 were assessed annually through testing previously analyzed specimens, blind samples, or proficiency testing samples for three of three test systems in 2022 and one of three test systems 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. The following test systems were observed as present and available for use during the tour: Cepheid GeneXpert XVI test system - Group B Streptococcus and Chlamydia trachomatis/Neisseria gonorrhoeae tests BD Affirm (Trademark) VP88 microbial identification system - vaginitis panel test ROM Plus - rupture of membranes test Cepheid GeneXpert Bacterial Vaginosis, Vulvovaginal Candidiasis, and Trichomoniasis test was in use May 2023 through February 2024 as indicated in laboratory records and confirmed by the TC. 3. Assessment of test performance using previously analyzed specimens, internal blind samples, or external proficiency samples was required annually for all TP as</p>

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 TP3's 2022 annual competency evaluation forms for the above moderate complexity tests. 5. Blind sample competency assessments were not documented as completed on TP6's 2023 annual competency evaluation forms for the Cepheid GeneXpert tests. 6. The laboratory was unable to provide the missing blind sample evaluation documentation upon request. 7. In an interview at 11:40 p.m. on 05/01/24, the TC confirmed the above finding. .