

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0665003	<b>(X3) Date Survey Completed</b>  04/19/2022
<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>D6045</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure training for two of eight new testing personnel was performed and/or documented in 2021. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, Parasitology, and General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:10 a.m. on 04/19/22. 2. BD Affirm VPIII, Cepheid GeneXpert, and Annisure ROM testing kits were present and available for use during the tour. 3. Initial training documentation was required for new testing personnel as established in the Staff Orientation, Training, and Competency procedure found in the General Laboratory Policy and Procedure Manual. 4. Testing Personnel 10 (TP10) was hired in December 2021 and Testing Personnel 11 (TP11) was hired in July 2021 as indicated in laboratory records. 5. The following initial training documents were not found during review of personnel records: TP10: BD Affirm VPIII, Cepheid GeneXpert TP11: BD Affirm VPIII, Cepheid GeneXpert, Annisure ROM 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 12:00 p.m., the TC confirmed the above finding. .</p>
<b>D6046</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on observation, document review and interview with laboratory personnel, the technical consultant failed to perform each competency assessment in 2020 and 2021. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, Parasitology, and General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:10 a.m. on 04/19/22. 2. BD Affirm VPIII, Cepheid GeneXpert, and Amnisure ROM testing kits were present and available for use during the tour. 3. The TC was responsible for performing testing personnel competency assessments as established in the Laboratory Personnel Requirements and Responsibilities procedure found in the General Laboratory Policy and Procedure Manual. 4. Every competency assessment document reviewed on date of survey indicated non-TC personnel performed the semi-annual and annual competency assessments in 2020 and 2021. 5. In an interview at 11:15 a.m. on 08/26 /20, the TC confirmed the above finding. .

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for three of eight testing personnel hired in 2020 and 2021. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, Parasitology, and General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:10 a.m. on 04/19/22. 2. BD Affirm VPIII, Cepheid GeneXpert, and Amnisure ROM testing kits were present and available for use during the tour. 3. Competency evaluations were required semi-annually for new testing personnel as established in the Staff Orientation, Training, and Competency procedure found in the General Laboratory Policy and Procedure Manual. 4. Initial training was performed and documented for the following testing personnel (TP) as indicated in laboratory records: TP3: January 2021 TP4: March 2021 TP6: February 2021 5. The following semi-annual competency assessments were not found during review of personnel records: TP3: BD Affirm VPIII, Cepheid GeneXpert, Amnisure ROM TP4: BD Affirm VPIII, Amnisure ROM TP6: BD Affirm VPIII, Amnisure ROM 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 12:00 p.m. on 004 /19/22, the TC confirmed the above finding. .

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least annually for one of two tenured testing personnel in 2021. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, Parasitology, and General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:10 a. m. on 04/19/22. 2. BD Affirm VPIII, Cepheid GeneXpert, and Amnisure ROM testing kits were present and available for use during the tour. 3. Annual competency evaluations were required as established in the Staff Orientation, Training, and Competency procedure found in the General Laboratory Policy and Procedure Manual. 4. The 2021 BD Affirm VPIII competency assessment was not found for Testing Personnel 1 during review of personnel records. 5. The laboratory was unable to provide the missing document upon request. 6. In an interview at 12:00 p.m. on 04 /19/22, the TC confirmed the above finding.