Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2118284	03/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oakdale Ob/Gyn	11855 Ulysses Street Ne, Suite 240, Blaine, 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 Oakdale OB/GYN 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 validation survey performed on March 10, 2026. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1291 Test report 493.1413 Technical consultant responsibilities .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records from 2024 for at least 2 years. Findings are as follows: 1. The laboratory performed moderate complexity Bacteriology, Mycology, and Parasitology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 03/10/26. 2. The laboratory performed Bacteriology, Mycology, and Parasitology PT using the Wisconsin State Laboratory of Hygiene (WSLH) provider. 3. Proficiency testing documentation retention was required for at least two years as established in the Quality Assurance Plan found in the Laboratory Policy and Procedure Manual. 4. The WSLH 2024-Bacti_Viral 1 Proficiency Testing Evaluation documents were not present in laboratory records on date of survey. The laboratory was unable to provide the missing documents reviewed in 2024 upon request. 5. In an interview at 12:26 p. m. on 03/10/26, the TC confirmed the above finding. .
D5813	TEST REPORT CFR(s): 493.1291(g)

	(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure notification of critical values was documented in 2024, 2025, and 2026. Findings are as follows: 1. The laboratory performed moderate complexity General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 03/10/26. 2. Amnisure Rupture of Fetal Membrane test kits were observed as present and available for use during the tour. 3. A positive Amnisure result was defined as a critical value in the Amnisure Procedure found in the Laboratory Policy and Procedure Manual. 4. A policy or procedure requiring provider notification of critical values and documentation of this notification was not found during review of laboratory policies and procedures. 5. In an interview at 1:15 p.m. on 03/10/26, Testing Personnel 3 confirmed the above finding and indicated verbal notification of critical values was performed but not documented. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (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; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive initial training was performed and documented for one of one new testing personnel (TP) in 2024 and four of four new TP in 2025. Findings are as follows: 1. The laboratory performed moderate complexity General Immunology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 03/10/26. 2. Amnisure Rupture of Fetal Membrane test kits were observed as present and available for use during the tour. 3. Competency evaluation of testing personnel was required in all testing areas at time of hire, after 6 months of work, and annually thereafter as established in the Competency Testing procedure found in the Laboratory Policy and Procedure Manual. 4. The following TP received initial training and competency assessments as indicated on the Lab Training and Orientation Checklist documents found in personnel folders. See below. Initial TP2 7/25 TP5 4/24 TP6 3/25 TP10 9/25 TP11 1/25 5. The Lab Orientation Checklist did not include the Amnisure ROM test. The laboratory was unable to provide the missing training records upon request. 6. In interviews at 11:10 a.m. and 11:18 a.m. on 03/10/26, the TC and TP3, respectively, confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the

	staff must include, but are not limited to-- This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the technical consultant failed to perform initial semiannual, and/or annual competency assessments for six of seven testing personnel (TP) in 2024, ten of eleven TP in 2025, and one of one TP in 2026. Findings are as follows: 1. The laboratory performed moderate complexity Bacteriology, Mycology, Parasitology, and General Immunology testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 03/10/26. 2. A Cepheid GeneXpert System and Amnisure Rupture of Fetal Membrane test kits were observed as present and available for use during the tour. The laboratory performed Group B Streptococcus, Chlamydia /Gonorrhea, and a Multiplex Vaginal Panel using the GeneXpert system. 3. The Medical Director was responsible for moderate complexity testing personnel competency evaluations as established in the Competency Testing procedure found in the Laboratory Policy and Procedure Manual 4. Competency assessments were performed by TP3 for the following TP as indicated in competency assessment documents found in personnel folders. See below. Initial 6 month Annual TP1 NA NA 12/24 12/25 TP2 7/25 1/26 TP4 NA NA 12/24 12/25 TP5 4/24 12/24 3/25 TP6 3 /25 8/25 TP7 NA NA 12/24 12/25 TP8 NA 1/24 11/25 TP9 NA NA 12/24 12/25 TP10 9/25 due TP11 1/25 8/25 5. A high school diploma and an Associates of Applied Science in Medical Assisting degree were found in TP3's personnel records. This education did not meet the minimum required to perform moderate complexity competency assessments. 6. In an interview at 11:25 a.m. on 03/10/26, the TC confirmed the above finding.