Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2159270	11/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Clinics Ladysmith	1101 Lake Ave W, Ladysmith, WI	

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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain test requisitions or authorization for patient testing performed after the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey and the current CLIA recertification survey for sixteen of twenty-two months. Findings include: 1. Review of laboratory records revealed no evidence of test requisitions or authorization for patient testing performed from January 5, 2023 through April 30, 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, and confirmed that laboratory did not retain patient test requisitions or authorizations for testing performed prior to the change of ownership.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory records and interview with the

	technical consultant, the laboratory did not retain analytical system records for one of one Abbott I-Stat chemistry analyzers for testing performed from January 5, 2023 through April 30, 2024. Findings include: 1. Review of laboratory records for the Abbott I-Stat chemistry analyzer revealed no evidence of quality control, maintenance, calibration and calibration verification records from January 5, 2023 through April 30, 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, confirmed that laboratory did not retain analytical system records for the Abbott I-Stat chemistry analyzer for testing performed prior to the change of ownership. Item 2 Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain analytical system records for one of one Sysmex XP-300 hematology analyzers for testing performed from January 5, 2023 through April 30, 2024. Findings include: 1. Review of laboratory records for the Sysmex XP-300 hematology analyzer revealed no evidence of quality control, maintenance, calibration and calibration verification records from January 5, 2023 through April 30, 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, confirmed that laboratory did not retain analytical system records for the Sysmex XP-300 analyzer for testing performed prior to the change of ownership.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(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 surveyor review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the technical consultant, the laboratory did not retain the PT records for three of three events in 2023 and one of one event in 2024. Findings include: 1. Review of WSLH PT records showed no evidence of testing records, signed attestation statements, PT result scores from the provider and documentation of result review for all events in 2023 and the first event of 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, and confirmed that laboratory did not retain PT records prior to the change of ownership.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain quality system assessment records between the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey and the current CLIA recertification survey for sixteen of twenty-two months. Findings include: 1. Review of laboratory records revealed no evidence of quality system assessments performed from January 5, 2023 through April 30, 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, and confirmed

	that laboratory did not retain quality system assessment records performed prior to the change of ownership.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not retain patient testing reports, and could not retrieve a copy, from the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey and the current CLIA recertification survey for sixteen of twenty-two months. Findings include: 1. Review of laboratory records revealed no evidence of patient testing reports from January 5, 2023 through April 30, 2024. 2. Interview with the technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, and confirmed that laboratory did not retain patient testing reports, and could not retrieve a copy, of testing performed prior to the change of ownership.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory director did assure compliance with the applicable regulations pertaining to retention requirements at CFR 493.1105. Findings include: 1. Review of patient testing records showed no evidence of test requisitions or authorizations from January 5, 2023 and April 30, 2024. 2. Review of analytical records showed no evidence of quality control, maintenance, calibration or calibration verification records for the Abbott I-Stat chemistry analyzer and the Sysmex XP-300 hematology analyzer from January 5, 2023 and April 30, 2024. 3. Review of the proficiency testing (PT) records showed no evidence of testing records, signed attestation statements, PT result and scores from the provider and documentation of result review for PT in 2023 and the first event of 2024. 4. Review of laboratory records showed no evidence of quality system assessments performed from January 5, 2023 and April 30, 2024. 5. Review of patient testing records showed no evidence of patient test reports from January 5, 2023 and April 30, 2024. 6. Interview with the

	technical consultant on November 5, 2024, at 9:15 AM stated the change of ownership from Prevea to Oakleaf Clinics on May 1, 2024, and confirmed that laboratory director did assure compliance with the applicable regulations pertaining to retention requirements at CFR 493.1105.