Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2095211	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Clinics Menomonie	2919 Stout Road, Menomonie, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing (PT) and laboratory records and interview with the Laboratory Director, the laboratory did not enroll in a PT program that included five samples three times per year for two of the last two years for seven regulated analytes tested with the i-STAT CHEM8+ cartridge. The laboratory's chemistry PT enrollment did not meet the criteria in subpart I of this part. Findings include: 1. Review of American Proficiency Institute (API) Core Chemistry PT records for 2024 and 2025 showed the laboratory participated in the Core Chemistry program in event three in 2024 and events one and two in 2025. The PT reports showed the laboratory evaluated only two samples during each event with i-STAT CHEM8+ cartridges for the following regulated analytes: chloride, creatinine, glucose, potassium, sodium, carbon dioxide, and urea nitrogen. The report showed no other results for these regulated analytes. 2. Review of i-STAT verification records showed the laboratory started testing CHEM8+ cartridges with the i-STAT analyzer on July 15, 2024. 3. Review of the laboratory test list showed no other method for testing the regulated analytes included in the CHEM8+ panel. 4. Interview with the Laboratory Director on May 14, 2025, at 10:35 AM confirmed the laboratory had not enrolled in a PT program that met the criteria in subpart I requiring the testing of five

	samples three times per year for the seven regulated analytes included in the i-STAT CHEM8+ cartridge.
D2004	ENROLLMENT CFR(s): 493.801(a)(3) (a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records, federal Certification and Survey Provider Enhanced Reports (CASPER), and interview with the Laboratory Director, the laboratory changed hematology and chemistry PT programs after event one in 2024 and did not participate in a single approved PT program for one of the last two calendar years. Findings include: 1. Review of the laboratory's PT records showed the laboratory participated in the American Proficiency Institute (API) PT program for hematology and chemistry in event three in 2024 and event one in 2025. Further review showed no PT records prior to event 3 in 2024. 2. Review of CASPER 155D 'Individual Laboratory Profile' report showed the laboratory received hematology PT results from API for event 3 in 2024 and event one in 2025. The report showed the laboratory received chemistry and hematology results for event one in 2024 from the Wisconsin State Laboratory of Hygiene (WSLH) PT program. 3. Interview with the Laboratory Director on May 14, 2025, at 10:35 AM confirmed the laboratory enrolled with API as their PT provider starting with event three in 2024.
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 email communication submitted to the State Agency and laboratory records and interview with the Laboratory Director, the laboratory did not retain test requisitions or authorization for patient testing performed after the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey on August 30, 2023, until April 21, 2024, eight of eight months. Findings include: 1. Review of email communication submitted to the State Agency by the previous owners of the laboratory showed the previous owners terminated their CLIA certificate for this laboratory effective April 21, 2024. 2. Review of laboratory records revealed no evidence of test requisitions or authorization for patient testing performed from August 30, 2023, until April 21, 2024. 3. Interview with the current Laboratory Director on May 14, 2025, at 12:30 PM confirmed the laboratory did not retain patient test requisitions or authorizations for testing performed under the previous owners of the laboratory.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)

	Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on surveyor review of email communication submitted to the State Agency and procedures and interview with the Laboratory Director, the laboratory did not retain test procedures that were in use from the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey on August 30, 2023, until April 21, 2024, eight of eight months. Findings include: 1. Review of email communication submitted to the State Agency by the previous owners of the laboratory showed the previous owners terminated their CLIA certificate for this laboratory effective April 21, 2024. 2. Review of laboratory procedures revealed no evidence of test procedures used by the laboratory from August 30, 2023, until April 21, 2024. 3. Interview with the current Laboratory Director on May 14, 2025, at 12:30 PM confirmed the laboratory did not retain test procedures for testing performed under the previous owners of the laboratory.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on surveyor review of email communication submitted to the State Agency and laboratory records and interview with the Laboratory Director, the laboratory did not retain quality control and patient test records for testing performed on two of two non-waived analyzers used after the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey on August 30, 2023, until April 21, 2024, eight of eight months. Findings include: 1. Review of email communication submitted to the State Agency by the previous owners of the laboratory showed the previous owners terminated their CLIA certificate for this laboratory effective April 21, 2024. 2. Review of laboratory records revealed no evidence of quality control or maintenance, calibration and calibration verification records or patient test records for testing performed from August 30, 2023, until April 21, 2024, on the i-STAT chemistry analyzer or the Sysmex hematology analyzer. 3. Interview with the current Laboratory Director on May 14, 2025, at 12:30 PM confirmed the laboratory did not retain analytic system records including quality control, maintenance, calibration and calibration verification and patient test records for testing performed under the previous owners of the laboratory from August 30, 2023, until April 21, 2024.
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 surveyor review of email communication submitted to the State Agency and proficiency testing (PT) records and interview with the Laboratory Director, the laboratory did not retain records for PT testing performed after the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey on August 30, 2023, until April 21, 2024, two of two events. Findings include: 1. Review of email communication submitted to the State Agency by the previous owners of the laboratory showed the previous owners terminated their CLIA certificate for this laboratory effective April 21, 2024. 2. Review of laboratory records revealed no evidence of PT records for event 3 in 2023 or event 1 in 2024. 3. Interview with the current Laboratory Director on May 14, 2025, at 12:30 PM confirmed the laboratory did not retain records for PT testing performed under the previous owners of the laboratory.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (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. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) 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 email communication submitted to the State Agency and patient reports and interview with the Laboratory Director, the laboratory did not retain test reports for patient testing performed after the previous Clinical Laboratory Improvement Amendments (CLIA) recertification survey on August 30, 2023, until April 21, 2024. Findings include: 1. Review of email communication submitted to the State Agency by the previous owners of the laboratory showed the previous owners terminated their CLIA certificate for this laboratory effective April 21, 2024. 2. Review of laboratory records revealed no evidence of test reports for patient testing performed from August 30, 2023, until April 21, 2024. 3. Interview with the current Laboratory Director on May 14, 2025, at 12:30 PM confirmed the laboratory did not retain patient test reports for testing performed under the previous owners of the laboratory.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, proficiency testing (PT) and laboratory records, and interview with the Laboratory Director, the laboratory had not verified the accuracy of the potassium hydroxide (KOH) test procedure for dermatology samples, including skin, hair or nails. Findings include: 1. Review of procedures showed the 'KOH Prep Hair, Skin, and Nails' procedure was effective June 4, 2024. 2. Review of PT records from the American Proficiency Institute (API) from 2024 and

	2025 showed no evidence the laboratory used proficiency testing samples to verify the accuracy of dermatology sample KOH testing. 3. Review of laboratory quality records showed no evidence of twice annual accuracy verification for KOH testing of hair, skin, and nails. 4. Interview with the Laboratory Director on May 14, 2025, at 10:35 AM confirmed the laboratory had not verified accuracy twice annually for the KOH test with hair, skin, or nail samples.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Laboratory Director, the laboratory did not perform quarterly maintenance for the Sysmex XP300 analyzer as required by the manufacturer. The laboratory had not documented quarterly maintenance in two of two quarters between August 2024 and March 2025. Findings include: 1. Review of the 'XP-300 Maintenance Logs' from August 2024 through April 2025 showed testing personnel only documented the quarterly maintenance, "Clean Sample Rotor Valve (SRV)" in March 2025. 2. Interview with the Laboratory Director on May 14, 2025, at 11:45 AM confirmed the laboratory had not documented cleaning of the sample rotor valve in the two quarters between August 2024 and February 2025.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs from January through March 2025 and interview with the Laboratory Director, the laboratory did not document corrective action when humidity readings were outside the acceptable range for 65 of 90 days. Findings include: 1. Review of temperature logs from January through March 2025 showed the acceptable room humidity level was 20 - 85%. Further review showed testing personnel recorded the humidity as 19%, which is below the acceptable range, on 65 of 90 days. Month / total recorded days / days with unacceptable humidity January / 31 / 31 February / 28 / 23 March / 31 / 11 The logs showed no documented corrective action when the humidity was below the acceptable range. 2. Interview with the Laboratory Director on May 14, 2025, at 11:45 AM confirmed the laboratory did not document corrective action when the humidity readings were outside the defined acceptable range.