Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2171289	04/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Clinics- Chippewa	855 Lakeland Drive, Chippewa Falls, 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
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 supervisor (Staff A), the laboratory changed PT providers for 21 of 23 analytes in the chemistry specialty (subspecialties: routine chemistry and endocrinology) after two out of three PT events in 2025 and did not participate in a single approved PT program for the 21 analytes in 2025. Findings include: 1. Review of PT records and reports for 21 analytes in the chemistry specialty in 2025 showed the laboratory participated in the Wisconsin State Laboratory of Hygiene (WSLH) PT program for events one and two in 2025. Records for event three in 2025 showed the laboratory participated in the American Proficiency Institute (API) PT program. 2. Review of the CASPER 155D Individual Laboratory Profile report showed the laboratory received results for 23 analytes in the chemistry specialty. Further review showed for 21 analytes in the chemistry specialty, the laboratory received results from the WSLH PT program for the first and second event in 2025 and received results from the API PT program for the third event in 2025. 3. Interview with Staff A on April 16, 2026, at 12: 25 PM confirmed the laboratory changed PT providers from WSLH to API after the second event in 2025. The laboratory submitted results to WSLH for the first and second event in 2025. For event three, the laboratory submitted results to API and did not submit results to WSLH to complete the 2025 year with the WSLH PT provider for 21 analytes in the chemistry specialty.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing (PT) records from the Wisconsin State Laboratory of Hygiene (WSLH) PT program, and interview with the laboratory supervisor (Staff A), the laboratory did not examine or test the PT samples in the same manner as its patient specimens for hematology cell identification for one of three events in 2025. Findings include: 1. Review of the 'Proficiency Review - Chippewa Falls' form for hematology PT event one in 2025 revealed Staff D and Staff F performed the testing. The form also had a sticky note addressed to Staff D and F asking, "Did the slides get divided between techs when reporting them?" The response was, "No. We both did them independently and compared results all in agreement." 2. During an interview with Staff A on April 16, 2026, at 1:50 PM, Staff A confirmed both testing personnel identified all images for the event and compared results. The interview further confirmed testing personnel independently evaluate and report the cell identification as part of the manual differential test on patient specimens and therefore the laboratory did not examine or test PT samples in the same manner as it tests patient specimens for one of three hematology PT events in 2025.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), competency assessment records, and interview with the technical consultant (Staff B), the laboratory did not follow their competency assessment procedures while performing direct observation (DO) of testing personnel for three of four competency assessment records reviewed. Findings include: 1. Review of the laboratory's procedure, '6 Step Competency Testing' stated in step 5.0, in part, "The following six procedures will be directly observed by the technical consultant. 1. Direct Observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing." 2. Review of Form CMS-209 showed Staff B was the sole staff member holding the technical consultant position. 3. Review of the laboratory's 2025 'Competence Assessment Record' forms for the Vitros 350 test system for Staff D and E and the Triage Biosite D dimer test system for Staff E showed Staff C performed the direct observation portion of the assessment. 4. Interview with Staff B on April 16, 2026, at 9:45 AM confirmed that Staff C performed competency assessments of

	testing personnel and confirmed the laboratory did not follow their procedure which required the technical consultant to perform the direct observation as part of the competency assessment.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing (PT) records from the Wisconsin State Laboratory of Hygiene (WSLH) PT program and interview with the laboratory supervisor (Staff A), the laboratory did not identify that the laboratory's results were out of range and did not verify the accuracy of four out of five thyroid stimulating hormone (TSH) results when the PT program did not obtain the agreement required for scoring in the chemistry/endocrinology PT event one in 2025. Findings include: 1. Review of the WSLH PT Evaluation report for the chemistry /endocrinology PT event one in 2025 showed four out of the five samples for TSH were not scored and indicated, "Non-consensus - Self-assessment Needed". The report showed, in part, the four non-consensus results for TSH: Sample | Result | Mean | Range CET-1 | 4.15 | 3.27 | 2.62 - 3.92 CET-2 | 1.31 | 1.01 | 0.81 - 1.21 CET-3 | 8.61 | 7.08 | 5.66 - 8.50 CET-5 | 2.67 | 2.13 | 1.70 - 2.56 2. Review of the 'Proficiency Test Corrective Action Checklist Form' completed for the event revealed the laboratory performed a self-assessment by taking the mean result from the peer group instead of the laboratory's result. There was no evidence the laboratory took further action to verify the accuracy of the TSH test. 3. Interview with Staff A on April 16, 2026, at 1: 48 PM confirmed the laboratory's self-assessment did not identify that the laboratory's results were out of range and did not verify the accuracy for the four of five TSH PT results that did not obtain the agreement required for scoring in the chemistry /endocrinology event one of 2025.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of a chemistry test report and laboratory procedures, and interview with the technical consultant (Staff B), the test result unit of measurement shown on the test report was different from the approved unit of measurement for one

	of twelve chemistry analytes reviewed. Findings include: 1. Review of the unit of measurement of a chemistry test report from January 21, 2026, showed the unit of measurement for the carbon dioxide (CO2) test was "Meq/L", or milliequivalents per liter. 2. Review of the laboratory procedure, 'Carbon dioxide, Vitros XT 3400', revealed the laboratory's unit of measurement was "mmol/L", or milimoles per liter. 3. Interview with Staff B on April 16, 2026, at 3:55 PM confirmed the procedure contained the correct unit of measurement and that the unit of measurement in test report for CO2 was not accurate. D5805 is a repeat deficiency, previously cited on March 16, 2022.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory proficiency testing (PT) records from the Wisconsin State Laboratory of Hygiene (WSLH) PT program, and interview with the laboratory supervisor (Staff A), the laboratory director did not ensure that review of PT results identified problems that require corrective action for two of thirteen automated hematology parameters reported to the PT provider for event three in 2025. Findings include: 1. Review of the WSLH PT Evaluation report for hematology PT event three in 2025 showed the laboratory reported results for thirteen parameters from their hematology analyzer. Further review of the report showed the laboratory received two failing results out of five, a score of 60%, for both erythrocytes (RBCs) and hemoglobin (Hgb). The standard deviation index (SDI) for all samples showed a negative bias for both analytes. The report, in part, contained the data for RBCs and Hgb: Sample | Result | SDI | Range | Status RBCs: AT-11 | 5.29 | -2.14 | 5.34 - 5.78 | Fail AT-12 | 2.23 | -0.17 | 2.15 - 2.33 | Pass AT-13 | 4.30 | -2.26 | 4.33 - 4.69 | Fail AT-14 | 2.18 | -1.02 | 2.15 - 2.33 | Pass AT-15 | 4.43 | -0.49 | 4.30 - 4.66 | Pass Hgb: AT-11 | 17.6 | -2.35 | 17.7 - 19.1 | Fail AT-12 | 5.9 | -0.67 | 5.8 - 6.2 | Pass AT-13 | 13.1 | -2.14 | 13.2 - 14.2 | Fail AT-14 | 5.9 | -0.62 | 5.8 - 6.2 | Pass AT-15 | 13.5 | -0.42 | 13.1 - 14.1 | Pass 2. The laboratory documented their review using the 'Proficiency Review - Chippewa Falls' form and 'Proficiency Test Corrective Action Checklist Form' and circled "Random Error" for the PT failure classification. There was no evidence the laboratory took further action to review the report and identify the negative bias requiring corrective action. 3. Interview with Staff A on April 16, 2026, at 2:34 PM confirmed the laboratory review of the PT results did not identify the negative bias in RBC and Hgb PT results and that the laboratory director did not ensure that review of the PT results identified problems that require further investigation and corrective action. Item 2: Based on surveyor review of laboratory proficiency testing (PT) records from the American Proficiency Institute (API) PT programs, and interview with the laboratory supervisor (Staff A), the laboratory director did not ensure that review of PT results identified problems that required corrective action for one of 22 routine chemistry analytes reported to the PT provider for event three in 2025. Findings include: 1. Review of the API PT Comparative Evaluation report for chemistry - core event three for 2025 showed the laboratory reported results for 22 routine chemistry analytes. Further review of the report showed the laboratory received four unacceptable results out of five, a score of 20%, for creatine kinase (CK). The SDI for all samples showed a positive bias for CK. The report, in part,

	included the data for CK: Sample|Reported Result|Expected Result| SDI|Performance CH-11 | 108 | 68 - 103 | 2.4 | Unacceptable CH-12 | 225 | 148 - 222 | 1.6 | Unacceptable CH-13 | 47 | 31 - 47 | 1.6 | Acceptable CH-14 | 130 | 83 - 126 | 2.2 | Unacceptable CH-15 | 159 | 103 - 155 | 1.8 | Unacceptable 2. The laboratory documented their review using the 'Proficiency Review - Chippewa Falls' form and 'Proficiency Test Corrective Action Checklist Form' and circled "Random Error" for the PT failure classification. A comment in the corrective action section stated, "Just analyzer random error. After rerun the results were within." There was no evidence the laboratory took further action to review the report and identify the positive bias requiring corrective action. 3. Interview with Staff A on April 16, 2026, at 2:40 PM confirmed the review of the PT results did not identify the positive bias in the CK PT results and that the laboratory director did not ensure that review of the PT results identified problems that required further investigation and corrective action.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the laboratory supervisor (Staff A), the laboratory director did not ensure the laboratory followed an approved corrective action plan for one analyte with unacceptable results of 27 analytes in the chemistry specialty PT event one in 2026. Findings include: 1. Review of American Proficiency Institute (API) PT Comparative Evaluation report for chemistry - core event one in 2026 records showed the laboratory received two unacceptable results out of five, a score of 60%, on samples tested for neonatal total bilirubin. The report, in part, showed the following data for Bilirubin, Total (Neonatal): Sample | Reported Result | Expected Result | SDI | Performance NB-01 | 18.9 | 12.2 - 18.5 | 9.5 | Unacceptable NB-02 | 0.4 | 0.0 - 0.4 | - | Acceptable NB-03 | 4.2 | 2.6 - 3.9 | 3.2 | Unacceptable NB-04 | 7.8 | 5.2 - 7.9 | 2.6 | Acceptable NB-05 | 21.3 | 14.5 - 21.8 | 2.5 | Acceptable 2. The laboratory documented their review using the 'Proficiency Review - Chippewa Falls' form and 'Proficiency Test Corrective Action Checklist Form'. The investigation identified equipment error, noting issues with the total bilirubin reagent, and random error. The record indicated the laboratory identified that the error could affect patient results. Further review showed no evidence the laboratory's investigation and corrective action plan included an evaluation of patient results. 3. Interview with Staff A on April 16, 2026, at 1:50 PM confirmed the laboratory director did not ensure the laboratory completed an evaluation of patient results when the laboratory identified possible patient impact in the corrective action plan for the unacceptable PT results in the chemistry PT event one in 2026.