Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2303894	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Clinics Rice Lake	1024 N Main St, Rice Lake, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) (a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Surveyor Provider Enhanced Reporting (CASPER) reports,. laboratory and proficiency testing (PT) records, and interview with the Laboratory Director, the laboratory did not report proficiency test results to Health and Human Services (HHS) for four of four non-waived programs since ordering PT samples from the American Proficiency Institute (API) on June 9, 2025. Findings include: 1. Surveyor attempts on February 2, 2026, to create a CASPER report 0155D (Individual Laboratory Profile) showing PT results for this laboratory were unsuccessful, there were no records available for this laboratory in the federal database. 2. Review of the laboratory's records from 2025 showed the laboratory reported non-waived test results in chemistry, hematology, mycology and urinalysis. 3a. Review of the API "2025 Order Confirmation" report for this laboratory showed the confirmation included the following statement, "CLIA number not on file - please call customer service at 800-333-0958". 3b. Review of the API "2026 Order Confirmation" report for this laboratory showed the confirmation included the following statement, "CLIA number not on file - please call customer service at 800-333-0958". 4. Interview with the Laboratory Director on February 4, 2026, at 9:15 AM confirmed the laboratory performed non-waived testing in hematology, chemistry, mycology, and urinalysis and confirmed the laboratory had not provided the CLIA number to API to allow reporting of the PT results to HHS.
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 procedures and interview with the laboratory director, the laboratory director did not follow the laboratory's PT policy for evaluation of one of one analyte with unsatisfactory results from the American Proficiency Institute (API) in the 2025 hematology / coagulation third event. Findings include: 1. The laboratory procedure, "Proficiency Testing Policy", showed the following in the 'Unsatisfactory Proficiency Testing (PT) Performance' section. "Unsatisfactory performance for 1 or more analytes on an event will receive a PT Exception Summary (PTES) report. Laboratory must: *Investigate problem *Determine cause *Implement corrective action *Conduct self-investigation using the Proficiency Test Corrective Action Checklist Form" 2. Review of the API "Proficiency Testing Performance Evaluation" report from the hematology / coagulation third event in 2025 showed the following unacceptable hematocrit results identified by API. The report showed an overall score of 60% for hematocrit testing. Sample | reported result | expected result range | performance HEM-11 | 38.6 % | 39.1 - 42.5 % | unacceptable HEM-13 | 32.1 % | 32.2 - 35.0 % | unacceptable 3. Review of the laboratory's PT records showed no evidence of a completed 'PT Exception Summary' or a 'Proficiency Test Corrective Action Checklist Form'. 4. Interview with the laboratory director on February 4, 2026, at 9:15 AM confirmed the laboratory had two unacceptable hematocrit results in the third API event in 2025 resulting in unsatisfactory performance. The interview also confirmed the laboratory did not complete the required forms for documentation of the investigation and corrective actions taken.