

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0989506	(X3) Date Survey Completed 07/19/2024
Name of Provider or Supplier Oakleaf Clinics Sc	Street Address, City, State 3802 W Oakwood Mall Dr, Eau Claire, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of a Centers for Medicare and Medicaid Services (CMS) Form 116 'Application for Certification' and laboratory procedures and interview with the Technical Consultant, the current laboratory director had not approved, signed, and dated four of four random procedures reviewed since assuming the role of laboratory director on April 29, 2024. Findings include: 1. Review of a CMS Form 116 submitted by the laboratory to the State CLIA office showed the laboratory requested a laboratory director change to a pathologist (Staff A) effective April 29, 2024. 2. Review of four random laboratory procedures (Troponin, Urine Microscopics, Vitros XT3400 Chemistry, and Affinion II ACR) showed no evidence of approval by Staff A. 3. Interview with the Technical Consultant on July 19, 2024, at 1:30 PM confirmed Staff A had not approved, signed, and dated the laboratory procedures since assuming the role of laboratory director on April 29, 2024.</p>