

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397620	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Tc Fam Med Clintonville	Street Address, City, State 370 S Main Street, Clintonville, 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 laboratory records and interview with the Manager of Laboratory Services, the laboratory director did not approve the Siemens epoc blood analysis system procedure until January 25, 2021, six days after the laboratory started patient testing with the test system. Findings include: 1. Review of the 'Document Change Review Request Form' for the Siemens epoc BGEM Orange Test Card procedure shows the laboratory director approved the procedure on January 25, 2021. 2. Interview with the Manager of Laboratory Services (Staff A) on March 16, 2021 at 12:20 PM revealed the laboratory used the Siemens epoc blood analysis system for patient testing as of January 19, 2021. Further interview confirmed the laboratory director did not approve the procedure before the laboratory began patient testing with the test system.</p>