

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405365	(X3) Date Survey Completed 03/24/2021
Name of Provider or Supplier Sanford Worthington Medical Center	Street Address, City, State 1018 6th Ave, Worthington, MN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <ul style="list-style-type: none"> 1. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain 1 of 2 2020 calibration verification records for a Hematology (Coagulation) analyzer for at least 2 years. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 03/24/21. 2. A Stago STA Compact Max coagulation analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer in June 2020 as indicated by the GS during the tour and confirmed by laboratory records. 3. Calibration verification was required every 6 months as established in the D-Dimer Worthington procedure located in the Coagulation Manual. 4. The calibration verification documents from December 2020 were not found during review of laboratory records. The laboratory was unable to provide the missing documents upon request as the original documents had not been retained and calibration records were not retrievable from the analyzer software on date of survey. 5. In an interview at 4:50 p.m. on 03/24/21, the GS confirmed the above finding.