Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396448	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Health System Sparta Clinic	1111 West Wisconsin Street, Sparta, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on surveyor review of records for the Roche c111 chemistry analyzer, observation of the analyzer, and interviews with Testing Personnel and the Laboratory Director, the laboratory did not implement a method to ensure accessible retention of calibration records for seven of seven tests for which testing personnel performed calibrations. Findings include: 1. Review of instrument records for the Roche c111 chemistry analyzer showed no evidence of calibration records for alkaline phosphatase, alanine transaminase, bilirubin, creatinine, glucose, blood urea nitrogen, or lipase. 2. Observation of the c111 analyzer on May 15, 2024, at 11:45 AM revealed current calibration data was available on the analyzer. During the observation, Testing Personnel, Staff B, confirmed they were not able to access historic calibration data on the analyzer without attempting to access the data on a flash drive used for data backup. Further interview confirmed Staff B had not used the flash drive to access historic data and could not confirm the past calibration data was available on the drive. 3. Interview with the Laboratory Director by email on May 16, 2024, at 7:52 AM confirmed the data on the flash drive was not accessible without addressing security concerns and confirmed the laboratory needed a different method of retention.
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 the submitted Centers for Medicare and Medicaid (CMS) Form CMS-209 (Laboratory Personnel Report), competence evaluation records, and procedures and interview with the Laboratory Director, the laboratory did not establish and follow written policies and procedures to assess the competence of one of one clinical consultant. Findings include: 1. Review of the Form CMS-209 submitted for the survey showed one clinical consultant identified, Staff A. 2. Review of competence evaluations records showed no evidence the laboratory director evaluated the competence of Staff A in performing their assigned clinical consultant responsibilities. 3. Review of the procedure, 'Quality Assurance for Laboratory Testing, Lab 0135', that included competence assessment policies, showed no evidence of a process for evaluation of the competence of the clinical consultant in performing their responsibilities. 4. Interview with the Laboratory Director on May 15, 2024, at 9:40 AM confirmed the laboratory had not established procedures to evaluate employee competence in performing the clinical consultant responsibilities. Further interview confirmed the director had not evaluated competence of the clinical consultant in performing their delegated responsibilities.