Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396499	05/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Health System Viroqua Clinic	407 S Main St Ste 200, Viroqua, 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
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 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 competence evaluation records showed no evidence the laboratory director evaluated the competence of a clinical consultant. 2. 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. 3. Interview with the Laboratory Director on May 16, 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 delegated the clinical consultant responsibilities to Staff A and confirmed the director had not evaluated competence of Staff A in performing their delegated responsibilities.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the laboratory director, the laboratory did not document the initiation date for one of one new test system with the procedure. The 'Sysmex XN-450/XN-550 Complete Blood Count and Parameters - Whole Blood, Lab -1532' procedure showed no initiation date for this laboratory. Findings include: 1. Review of laboratory records showed the laboratory verified performance specifications for the Sysmex XN-550 analyzer in February 2024. 2. Review of the procedure, 'Sysmex XN-450/XN-550 Complete Blood Count and Parameters - Whole Blood, Lab -1532', showed no indication of the initial date of use for the Sysmex XN-550 analyzer in this laboratory. 3. Interview with the laboratory director on May 16, 2024, at 10:00 AM confirmed the procedure did not include the initial date of use for the Sysmex XN-550 at this laboratory.