

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396462	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Gundersen Health System Tomah Clinic	Street Address, City, State 505 Gopher Drive, Tomah, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form CMS-209 (Laboratory Personnel Report), competency evaluation records and procedures and interview with the Regional Laboratory and POCT Clinical Manager, staff A, the laboratory did not establish and follow written policies and procedures to assess the competence for one of one clinical consultant. Findings include: 1. Review of the Form CMS-209 submitted for survey showed one clinical consultant identified, staff B. 2. Review of the competency evaluation records showed no evidence the laboratory director evaluated the competence of staff B in performing their assigned clinical consultant responsibilities. 3. Review of laboratory procedures related to competency assessment showed no evidence of a process for evaluation of the competence of the clinical consultant in performing their delegated responsibilities. 4. Interview with staff A on May 22, 2024, at 11:10 AM confirmed the laboratory had not established procedures to evaluate competency for the clinical consultant and the laboratory director had not evaluated the competency of the clinical consultant for their delegated responsibilities.</p>
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of competency assessment records and interview with the Regional Laboratory and POCT Clinical Manager, staff A, the technical consultant did not document the direct observation of routine patient testing for five of five Provider Performed Microscopy (PPM) testing personnel. Findings include: 1. Review of competency assessment records showed no evidence of direct observation of routine fern testing for PPM testing personnel. 2. Interview with staff A on May 22, 2024, at 11:20 AM confirmed the technical consultant did not document direct observation of routine testing for PPM testing personnel.