

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396909	(X3) Date Survey Completed 07/10/2024
Name of Provider or Supplier Tri-County Memorial Hospital	Street Address, City, State 18601 Lincoln St, Whitehall, 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 laboratory procedures and competency assessment records and interview with the general supervisor, the laboratory did not follow written procedures to assess employee competency for one of three new testing personnel. Findings include: 1. Review of "Quality Assessment for Laboratory Testing" procedure stated "The supervisor, technical leader or designee if responsible for competency of all testing personnel. " 2. Review of "New Hire Laboratory Tech Competency" form for testing personnel, staff A, showed a comment "Staff A is authorized to perform all testing in those areas competency has been documented." This comment was signed by staff A with no other signatures or initials indicating competency was assessed by the laboratory director, technical consultant, technical supervisor or general supervisor. 3. Interview with the general supervisor on July 9, 2024, at 10:15 AM confirmed the laboratory did not follow written procedures to assess employee competency.</p>
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures, quality control (QC) records, and patient testing report from the laboratory information system (LIS) and interview with the general supervisor, testing personnel did not test hematology controls every 24 hours for one of ninety-two patient testing days between February 21, 2023, and May 23, 2023, as required in the procedure. Findings include: 1. Review of "Sysmex XN-450 /XN-550 Complete Blood Count and Parameters-Whole Blood" stated "XN-L CHECK control levels 1, 2 and 3 will be run at least once every 24 hours prior to patient testing". 2. Review of QC records on the Sysmex Insight Raw Data Report for lot 3041 from February 21 to May 23, 2023, showed QC material was not tested on May 3, 2023. Further review showed QC was tested May 2, 2023, at 4:45 AM and May 4, 2023, at 3:51 AM. 3. Review of patient testing reports from the LIS showed fifteen patient samples were tested on May 3, 2023. 4. Interview with the general supervisor on July 10, 2024, at 10:05 AM confirmed testing personnel did not follow the procedure to test hematology controls every 24 hours of patient testing. This is a repeat deficiency from July 12-13, 2022.