

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2172713	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Gundersen Lutheran Medical Center	Street Address, City, State 1122 West Highway 61, Winona, 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
D0000	The Gunderson Lutheran Medical Center Winona Campus laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial survey performed on July 11, 2024. The following condition-level deficiency was cited: 493.1421 Laboratories performing moderate complexity testing: testing personnel The following standard-level deficiency was cited: 493.1423 Testing personnel qualifications .
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: . Based on personnel record review and interview and email communication with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing met the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: Documentation was not provided for one of fourteen testing personnel showing educational requirements for moderate complexity testing were met. See D6065. .</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a</p>

chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on document review and interview and email communication with laboratory personnel, the laboratory failed to ensure one of fourteen testing personnel had the required educational credentials to perform moderate complexity testing in 2023 and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology, Chemistry, and Hematology testing and Microscopic Examinations for bacteria, parasites, fungus, urine sediment, and rupture of fetal membranes as confirmed the Technical Supervisor (TS) during a tour of the laboratory at 8:35 a.m. on 07/11/24. The laboratory performed approximately 119,583 moderate complexity tests annually. 2. Documentation of a high school education was not found for Testing Personnel 6 (TP6) during review of laboratory documents. A Phlebotomy Certificate for TP6 was provided. 3. Survey document Form CMS-209, signed by the Laboratory Director on 07/09/24, listed TP6 as qualified to perform moderate complexity testing. 4. In an interview at 9:25 a.m. on 07/11/24, the TS confirmed documentation of a high school education was not present for TP6. The laboratory was given an opportunity to provide the credentials within five days of the survey. 5. In an email received at 8:43 a.m. on 07/16/24, the TS provided an incomplete high school transcript and indicated official documentation of a high school equivalency diploma had not been received for TP6.