

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0406224	<b>(X3) Date Survey Completed</b>  06/18/2025
<b>Name of Provider or Supplier</b>  Lakewood Health System	<b>Street Address, City, State</b>  49725 County 83, Staples, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Lakewood Health System 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 recertification survey performed on June 18, 2025. The following standard-level deficiencies were cited: 493.1451 Technical supervisor responsibilities .
<b>D6126</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi)</p> <p>(b)(8)(vi) Assessment of problem-solving skills; and</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure a documented evaluation of problem solving skills was completed during 2024 annual competency assessments for 1 of 16 hospital laboratory testing personnel. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 8:05 a.m. on 04/25/19. The following analyzers and equipment were observed as present and available for use during the tour of the laboratory: Cepheid GeneXpert Molecular Test System Gram stain kit Versa Trek Automated Microbial Detection System Sysmex XN 100 Automated Hematology Analyzer Nikon e400 microscope Ortho Workstation Immunohematology Analyzer 2. The laboratory's electronic Personnel Competency Assessment with Staff Ready procedure, located in the internal SharePoint folder, included a requirement to evaluate problem solving skills annually for each test system. 3. The 2024 Staff Ready Report for General Supervisor 3 (GS3) did not include assessment of problem solving skills for 10 of 24 test system areas. The problem solving assessment areas that were not included in GS3's report are listed below. Cepheid GeneXpert MVP Gram Stain Versa Trek blood cultures Vitros chemistry analyzer Urinalysis Sysmex XN 100</p>

hematology analyzer Manual differential Manual cell counts Semen analysis/Post Vasectomy Gel Blood Banking The laboratory was unable to provide documentation of GS3's 2024 problem solving assessments for the above test systems upon request.

4. In an interview at 9:55 a.m. on 06/18/25, the TS confirmed the above finding. .