

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0674215	<b>(X3) Date Survey Completed</b>  01/30/2024
<b>Name of Provider or Supplier</b>  Lakewood Health System-Eagle Valley Clinic	<b>Street Address, City, State</b>  815 Hwy 71 South, Eagle Bend, 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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve two of two moderate complexity testing procedures in use by the laboratory in 2022, 2023, and 2024. Findings are as follows:                      1. The laboratory performed moderate complexity Toxicology and Hematology testing as confirmed by Technical Consultant 2 (TC2) during a tour of the laboratory at 1:05 p.m. on 01/30/24. 2. The following moderate complexity testing equipment was observed as present and available for use during the tour: Toxicology - MEDTOXScan reader ( Drugs of Abuse testing) Hematology -Sysmex XP-300 analyzer (Complete Blood Count testing) 3. The laboratory maintained electronic procedures in the LakeNet SharePoint site. 4. Laboratory Director approval for the following testing procedures was not found during LakeNet SharePoint review on date of survey: MedTox Urine Drug Screen Procedure Sysmex XP-300 5. In an interview at 2:30 p.m. on 01/30/24, TC2 confirmed the above finding. .</p>