

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385384	<b>(X3) Date Survey Completed</b>  02/20/2025
<b>Name of Provider or Supplier</b>  Sanford Sheldon Medical Center	<b>Street Address, City, State</b>  118 North Seventh Avenue, Sheldon, IA	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of gram stain quality control (QC) records, patient test reports and the Gram Stain Procedure - Sheldon and confirmed by interview with technical supervisor (TS) #1 at 12:06 pm 2/20/2025, the laboratory failed to follow the gram stain procedure and perform QC with each patient for one of one patient reviewed on 12/4/2024. The findings include: 1. The Gram Stain Procedure - Sheldon states, "A premade QC slide containing gram positive and gram negative organisms will be stained daily with each patient sample or with each new lot change." 2. Patient identifier A had a gram stain performed on 12/4/2024. 3. The laboratory did not have documentation of gram stain QC being performed on 12/4/2024. 4. TS #1 confirmed the laboratory did not follow their procedure for performing gram stain QC.</p>