

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0394447	<b>(X3) Date Survey Completed</b>  01/22/2025
<b>Name of Provider or Supplier</b>  Kaukauna Clinic Sc	<b>Street Address, City, State</b>  305 E 12th St, Kaukauna, WI	
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>(d) 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 survey review of laboratory records and procedures and interview a technical consultant, staff A, the laboratory director did not sign and date two of two new analyzer procedures prior to patient use. Findings include: 1. Review of the Horiba Pentra C400 chemistry analyzer performance specification verification records showed the Pentra C400 go-live date was August 21, 2023. 2. Review of the Horiba Micros ES60 hematology analyzer performance specification verification records showed the Micros ES60 go-live date was March 12, 2024. 3. Review of the "Horiba Pentra C400 Chemistry Analyzer" and Horiba Micros ES60 Hematology Analyzer" procedures showed the laboratory director reviewed and signed the procedures on November 20, 2024. 4. Interview with staff A on January 22, 2025, at 12:07 PM confirmed the laboratory director did not sign and date new procedures prior to patient use.</p>