

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396419	<b>(X3) Date Survey Completed</b>  05/14/2024
<b>Name of Provider or Supplier</b>  Gundersen Health System Onalaska Clinic	<b>Street Address, City, State</b>  3111 Gundersen Dr, Onalaska, 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>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 surveyor review of electronic procedures and interview with the laboratory director, the director did not approve, sign, and date one of three procedures reviewed. Findings include: 1. Review of three procedures in the electronic document management system showed the 'Trauma Drugs of Abuse -Medtox, Lab-1008' procedure showed no evidence of approval by the laboratory director. 2. Interview with the laboratory director on May 14, 2024, at 1:30 PM confirmed the director had not signed and dated the procedure for testing performed on the Medtox analyzer.</p>
<b>D5409</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the laboratory director, the laboratory discontinued testing with the Werfen ACL Elite Coagulation analyzer and the Sysmex X1000 hematology analyzer procedures, two of two discontinued test systems reviewed, and did not retain the discontinued date with the procedures. Findings include: 1. Review of procedures for the ACL Elite coagulation analyzer and the Sysmex X1000 hematology analyzer showed no indication the laboratory discontinued use of the two test systems. 2. Interview with the laboratory director on</p>

May 14, 2024, at 11:20 AM confirmed the laboratory discontinued testing with the Elite coagulation analyzer in October 2022 and discontinued testing with the Sysmex X1000 analyzer on April 23, 2024. Further interview confirmed the laboratory had not retained the dates of discontinuance with the procedures for the two test systems.

**D6070**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor review of testing logs, patient test reports, and laboratory procedures and interview with the laboratory director, provider performed microscopy testing personnel did not follow the laboratory's procedures for reporting one of one vaginal wet prep result reviewed. Findings include: 1. Review of the testing log in the Occupational Health, Obstetrics, and Urology area of the clinic showed Patient 1 had a vaginal wet prep test performed on May 13, 2024, by a provider, Staff A. The log showed Staff A identified clue cells in the sample. 2. Review of the patient test report in the electronic medical record showed the provider entered, "BV again present on this exam" in the notes area of the patient record. No other results of the vaginal wet prep were evident in the record. 3. Review of the procedure, 'Point of Care Wet Preparation for Trichomonas, Yeast, and Clue Cells, Lab-0950' showed the procedure directed testing personnel to record results using EPIC's Enter/Edit function including results for Trichomonas, Yeast, and Clue Cells. 4. Interview with the laboratory director on May 14, 2024, at 9:50 AM confirmed Staff A did not follow the laboratory's procedures for reporting patient test results for provider performed microscopy testing.