

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0393832	<b>(X3) Date Survey Completed</b>  06/06/2024
<b>Name of Provider or Supplier</b>  Gundersen Boscobel Area Hospital And Clinics	<b>Street Address, City, State</b>  205 Parker St, Boscobel, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the large white freezer, review of temperature logs, and interview with a technical consultant, staff A, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the Maine Standards calibration verification material stored in the freezer for twenty-eight days of one hundred fifty-two days from January 1, 2024, through May 31, 2024. Findings include: 1. Observation of eight boxes of Maine Standards Validate calibration verification material used for chemistry analytes in the large white freezer on June 5, at 3:30 PM showed the manufacturer required storage at -10 to -25 degrees Celsius (C). 2. Review of the "Daily Temperature Monitoring Log" from January 1st through May 31, 2024, showed the defined acceptable temperature range for the large white freezer was -20 C or colder. Further review showed the following dates the temperature was colder than -25 C: January: 12, 16-17, 27 February: 25-27 March: 13, 22, 24 April: 7, 11, 19, 25-26, 29 May: 8-11, 13-14, 18, 24, 26-29 3. Interview with the staff A on June 5, 2024, at 3:35 PM confirmed the laboratory's acceptable range for the large white freezer was not consistent with the manufacturer's acceptable range for the Maine Standards Validate calibration verification material.</p>

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on survey review of a patient's chemistry test report and laboratory procedures and interview with a technical consultant, staff A, the reference ranges shown on the patient report were not the same as the approved reference ranges for two of six chemistry analytes reviewed. Findings include: 1. Review of the reference range of a chemistry test report from January 23, 2024, in the electronic medical record (EMR) for patient 1 (an adult female) showed the following expected ranges: Analyte /Reference range Sodium /135-146 milli moles/Liter (mmol/L) Potassium /3.4-5.0 mmol/L Chloride /96-108 mmol/L Creatinine /0.51-0.95 milligrams/deciliter (mg/dL) Calcium /8.6-10.0 mg/dL Glucose /70-99 mg/dL 2. Review of the individual chemistry procedures for each analyte showed the approved reference ranges for an adult female are: Analyte /Reference range Sodium /135-146 mmol/L Potassium /3.4-5.0 mmol/L Chloride /96-108 mmol/L Creatinine /0.6-1.1 mg/dL Calcium /8.5-10.4 mg/dL Glucose /70-99 mg/dL Further review showed the creatinine and calcium reference ranges in the procedure did not match the patient's test report. 3. Interview with staff A on June 6, 2024, at 12:50 PM confirmed the reference range for creatinine and calcium in the procedures were not the same as the test report. This is a repeat deficiency from July 14-15, 2022.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on surveyor review of quality control procedures and interview with the chemistry technical consultants, staff A and staff B (who is the technical leader for chemistry), the technical consultant for chemistry did not ensure parameters set for acceptable level of quality performance were maintained for two of two analytes reviewed. 1. Review of the "Quality Control Criteria for Chemistry" procedure stated: "7) A monthly review of all computer data is conducted by the technical leader. Unrecognized problems and potential problems are discussed, and recommended actions are instituted towards correcting problems or trend, including any clinically significant increases in imprecision." 2. Review of quality control reports for alkaline phosphatase from December 1, 2023, through April 30, 2023, showed the target mean and standard deviation (SD) for Lot number 92951 (level 1) was 111.1 and 5.0 and Lot number 92952 (level 2) was 419.7 and 15.0. Further review showed the target mean and SD were unchanged during this timeframe. 3. Review of quality control reports for alkaline phosphatase showed the following calculated mean and SD for each month were: Lot # 92951 Month / Calculated mean / Calculated SD / Comment

December / 107.6 / 15.0 January / 109.0 / 1.9 February / 108.2 / 2.4 / 18 of 29 results were below the target mean. March / 107.3 / 2.2 / 26 of 31 results were below the target mean. April / 105.6 / 2.0 / All 30 results were below the target mean. Lot # 92952 Month / Calculated mean / Calculated SD / Comment December / 411.9 / 4.0 / 24 of 31 results were below the target mean. January / 409.4 / 3.5 / 29 of 31 results were below the target mean. February / 406.9 / 4.5 / All 29 results were below the target mean. March / 405.4 / 3.7 / All 31 results were below the target mean. April / 401.4 / 4.2 / All 30 results were below the target mean. Further review showed the staff B reviewed the results monthly with no documentation of discussion or recommended action based on trending within the data. 4. Review of quality control reports for amylase from December 1, 2023, through April 30, 2023, showed the target mean and standard deviation (SD) Lot number 92952 (level 2) was 414.3 and 16.0. Further review showed the target mean and SD were unchanged during this timeframe. 5. Review of quality control reports for amylase showed the following calculated mean and SD for each month were: Lot # 92952 Month / Calculated mean / Calculated SD / Comment December / 405.8 / 2.8 / 30 of 31 results were below the target mean. January / 408.0 / 6.8 / 29 of 31 results were below the target mean. February / 428.8 / 2.2 / All 29 results were above the target mean. March / 428.1 / 2.1 / All 31 results were above the target mean. April / 427.4 / 2.3 / All 30 results were below the target mean. Further review showed the staff B reviewed the results monthly with no documentation of discussion or recommended action based on trending within the data. 6. Interview with staff A on June 5, 2024, at 2:30 PM confirmed the technical consultant for chemistry did not ensure parameters set for acceptable level of quality performance were maintained. 7. Interview with staff B (the chemistry lead and technical consultant) on June 5, 2024, at 2:50 PM confirmed the technical consultant did not follow the quality control procedure to discuss and recommend actions based on trends in quality control and did not ensure parameters set for acceptable level of quality performance were maintained.

**D6175**

**TESTING PERSONNEL RESPONSIBILITIES**  
 CFR(s): 493.1495(b)(1)

Each individual performing high 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 survey review of immunohematology logs and electronic medical record (EMR) and interview with the general supervisor, testing personnel did not report test results for one of one immunohematology report reviewed. Findings include: 1. Review of the immunohematology log showed patient 2 received emergency release transfused blood on December 23, 2023. Further review showed a type and screen, and unit crossmatches were performed on the patient. 2. Review of the EMR for patient 2 showed no test results for the type and screen and unit crossmatches. 3. Interview with the general supervisor on June 6, 2024, at 12:41 PM confirmed testing personnel did not report test results into the Laboratory Information System (LIS) for the immunohematology report reviewed and the results were not in the patient's chart.