

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393832	(X3) Date Survey Completed 08/09/2022
Name of Provider or Supplier Gundersen Boscobel Area Hospital And Clinics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and manufacturer's instructions and interview with the general supervisor, the laboratory had not performed the required two-month maintenance three of nine times and had not performed two of the three required maintenance items every six months on the Roche cobas c 311 analyzer from January 2021 through June 2022. Findings include: 1. Review of the "cobas c 311 analyzer Maintenance Logs" from January 2021 through June 2022 showed replacements of the ISE (ion selective electrode) measuring cartridges for sodium, potassium and chloride were to occur every two months. The records showed the laboratory replaced the electrodes quarterly in February, May, August, and November 2021, and February and May 2022. The logs showed the six-month maintenance tasks included cleaning the water inlet filter and cleaning the cooling fan. The laboratory did not document completion of these two items on any of the reviewed maintenance logs. 2. Review of the manufacturer's instructions for maintenance of the Roche c311 showed replacement of the ISE measuring cartridges must occur at least every two months and cleaning the inlet water filter and cooling fan must occur every six months. 3. Email correspondence with the general supervisor on August 9, 2022 at 2: 27 PM confirmed the laboratory did not change the ISE measuring cartridges on the Roche cobas c 311 every two months and confirmed the laboratory did not clean the water inlet filter or cooling fan every six months as required by the manufacturer.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p>

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 surveyor review of procedures, manufacturer's instructions and patient test reports and interview with the general supervisor, the interpretive information for opiates on the patient test report was not accurate on two of two test reports reviewed. Findings include: 1. Review of the "Trauma Drugs of Abuse - Medtox, Lab 8001" procedure showed the internally calibrated threshold for opiates was 100 ng/mL (nanograms per milliliter). 2. Review of the "Medtox Profile V MEDTOXScan Drugs of Abuse Test System Package Insert" showed the cutoff concentration for Opiates was either 100 ng/mL or 2000 ng/mL. 3. Review of test reports for patients one and two showed the cutoff for Opiates was 300 ng/mL. 4. Interview with the general supervisor on July 14, 2022 at 4:15 PM confirmed the cutoff found on the test report was not accurate.