| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D0404612 | 02/20/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gundersen St Elizabeth's Hospital And Clinics | 1200 Grant Blvd W, Wabasha, MN | |

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 |
|---|---|
| **D0000** | . The Gundersen St. Elizabeth's Hospital and Clinics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey completed on February 20, 2025. The following standard-level deficiencies were cited: 493.1254 Maintenance and function checks 493.1291 Test report . |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure function checks for one of four Chemistry analyzers were performed and documented as required in 2023 and 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 11:07 AM on 2/19/2025. 2. An Abbott iSTAT analyzer was observed as present and available for use during the tour. The laboratory used the iSTAT analyzer for Blood Gas testing. The iSTAT was also used as a back-up analyzer for Basic Metabolic Panel and Troponin testing. 3. Twice-annual verification of the iSTAT thermal probe was required by the manufacturer as indicated in the Abbott iSTAT System Manual and as established in the laboratory's Blood Gas (CG8+) iSTAT, Lab-0910 procedure provided by the laboratory on the date of survey. 4. Evidence of thermal probe verification was not found in laboratory maintenance records for 2023 and 2024. The laboratory was unable to provide this |

| | |
|---|---|
| | documentation upon request. 5. In an interview at 1:20 PM on 2/20/2025, the TC confirmed the twice-annual thermal probe verifications were not performed with routine maintenance of the iSTAT analyzer. . |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review, and interview with the laboratory personnel, the laboratory failed to ensure two Chemistry reference intervals were consistent between the procedure and a patient test report in 2023 and 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 11:07 AM on 2/19/2025. 2. The following Chemistry analyzers were observed as present and available for use during the tour of the laboratory: Roche C501 - the laboratory performed Ammonia (AMM) testing using this analyzer Roche E411 - the laboratory performed Free Thyroxine (FT4) testing using this analyzer 3. AMM reference intervals listed in the Ammonia (NH3) - Roche/Hitachi Cobas C Systems, Lab 4225 procedure provided by the laboratory were not consistent with those included on a patient test report from 6 /30/2023. FT4 reference intervals listed in the Free Thyroxine (FT4 IV) - Cobas E411, Lab 1594 procedure provided by the laboratory were not consistent with those included on a patient test report from 12/2/2024. See below. Analyte Procedure Test Report AMM (umol/L) 11-51 13-56 FT4 (ng/dL) 0.90-1.70 0.92-1.68 4. In an interview at 11:15 AM on 2/20/2025, the TC confirmed the above finding. . |