

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404612	(X3) Date Survey Completed 04/23/2021
Name of Provider or Supplier Gundersen St Elizabeth's Hospital And Clinics	Street Address, City, State 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of five 2020 non-graded proficiency testing (PT) results for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/23/21. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One Chemistry result from the second 2020 Chemistry PT event was not graded by API due to lack of participants. See below. Sample ID Analyte CH-01 through CH-05 Vancomycin 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summaries for the above samples were not present in laboratory records. Evaluation of the non-graded results was not found in laboratory records. 5. Evaluation of non-graded PT results was required as established in the Proficiency Testing Policy. The laboratory was unable to provide an evaluation of the non-graded results upon request. 6. In an interview at 11:50 a.m. on 04/23/21, the GS confirmed the above finding. .</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the reportable ranges obtained during performance verification activities for 2 Chemistry analyzers were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 04/23/21. 2. A Roche Cobas c501 chemistry analyzer and a Roche e411 chemistry analyzer were observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities were completed on 02/24/21 and the laboratory began testing patient specimens using these analyzers on 03/01/21 as indicated by the GS. Sodium (Na), Potassium (K), and Chloride (Cl) testing was performed on the c501 and Thyroid Stimulating Hormone (TSH) testing was performed on the e411. 4. The adopted upper and lower limit of the reportable ranges found in the Sodium, Potassium, Chloride (ISE)-Cobas c501 procedure and the TSH - Cobas e411 procedure for 4 of 4 analytes reviewed on date of survey did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Adopted Na 84.0-171.7 80-180 K 1.8-9.613 1.5-10 Cl 70.53-135.17 60-140 TSH 0.10-99.0 0.02-100 5. In interviews at 2:40 p.m. and 4:00 p.m. on 04/02/21, the GS confirmed the above findings and indicated the laboratory adopted the manufacturers analytical measurement ranges as their reportable ranges for the analytes. .