Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404612	12/20/2018
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the procedure manual included the reportable range for test results from a hematology instrument. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 10:05 a.m. 2. A Sysmex XS-1000i hematology analyzer was observed as present and available for use during the tour. 3. Review of the Complete Blood Count and Differential Using the Sysmex XS-1000i Hematology Analyzer procedure, located in the on-line Policy-stat procedure manual, revealed that

	the reportable range for Red Blood Cells, White Blood Cells, Hemoglobin and Platelets was not included in the procedure. 4. In an interview on 12/20/18 at 8:30 a. m., the GS confirmed the above findings. .
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 observation, document review and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between Chemistry and Coagulation procedures and patient test reports. Findings are as follows: The laboratory performed Chemistry and Coagulation testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 10:05 a.m. A. Immuno Chemistry 1. A Siemens Centaur CP immunoassay analyzer was observed as present and available for use during the tour. 2. The reference interval for Troponin I listed in the Siemens Advia Centaur CP THCG, CKMB, Ferritin, Troponin I, TSH, BNP and Vancomycin procedure, located in the on-line Policy-stat procedure manual, were not consistent with those included in the Reference Range Table, also located in the on-line Policy-stat procedure manual, or on the patient test report (Female - 84 years, Date performed = 12-19-17) reviewed on date of survey as indicated below: Procedure: Non-cardiac = 0.02 - 0.06 Cardiac = >0.10 Reference Range Table: 0.00 - 0.02 Patient Report; 0.00 - 0.02 3. In an interview on 12/19/18 at 2:00 p.m., the GS confirmed the above finding. B. Chemistry 1. A Ortho Vitros 5,1 chemistry analyzer was observed as present and available for use during the tour. 2. The reference interval for Creatinine listed in the Vitros 5,1 Analytes Table, located in the on-line Policy-stat procedure manual, were not consistent with those found on a patient test report (Male - 70 years, Date performed = 9-16-18) reviewed on date of survey as indicated below: Reference Range Table: Male = 0.52 - 1.04 Female = 0.66 - 1.25 Patient Report; 0.66 - 1.25 3. In an interview on 12/19/18 at 2:00 p.m., the GS confirmed the above finding C. Coagulation 1. A Sysmex CA-1500 coagulation analyzer was observed as present and available for use during the tour. 2. The D Dimer reference interval listed in the D Dimer (FEU) Innovance Sysmex CA-1500 procedure, located in the on-line Policy-stat procedure manual, were not consistent with those included in the Reference Range Table, also located in the on-line Policy-stat procedure manual, or on the patient test report (Male - 86 years, Date performed = 1-2-17) reviewed on date of survey as indicated below: Procedure: 0.00 - 0.59 Reference Range Table: 0.19 - 0.50 Patient Report; 0.19 - 0.50 3. In an interview on 12 /19/18 at 2:00 p.m., the GS confirmed the above finding. .
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by:

	. Based on document review and interview with laboratory personnel, the laboratory failed to establish procedures to ensure availability of testing in the event of the inoperability of testing methods, or availability of patient results in the event of of the inoperability of laboratory information systems (LIS) or electronic health record (EHR) systems. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Hematology, Coagulation, Immunology, Microbiology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 10:05 a.m. 2. Review of the on-line Policy-stat procedure manual failed to reveal the presence of LIS / EHR or testing method downtime procedures. The laboratory was unable to produce the procedures upon request. 3. In an interview on 12/19/18 at 2:30 p.m., the GS confirmed the above findings. .