Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404612	12/16/2022
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, record review, and and interview with laboratory staff, the laboratory failed to include step by step performance of the staining of a blood smear manual differential. Findings are as follows: 1. The laboratory performs manual blood smear differentials as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:45 a.m. on 12/16/22. 2. The microscope and staining materials used to perform the manual blood smear differential were observed as present and available for use during the tour of the laboratory. 3. Review of the current procedure, Differential: Counting and Morphology, Lab - 5074 directed staff to how to perform

	the smear of the blood and then straight to looking at the slide under the microscope after the slide had been stained. The procedure did not include a step by step procedure on how to stain the slide. 4. In an interview at 2:28 p.m. on 12/16/22, the GS confirmed the staining procedure was missing from the current procedure. At 2:55 p.m. on 12/16/22, the GS was able to provide a procedure, discontinued on 07/18/22, with the step by step staining procedure. .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, record review, and an interview with laboratory personnel, the laboratory failed to examine bottles of media and document as established in procedure. Findings are as follows: 1. The laboratory performs blood cultures under the subspecialty of Bacteriology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:45 a.m. on 12/16/22. 2. The BacT Alert was observed as present and available for use to perform blood cultures during the tour of the laboratory. 3. The BacT Alert Blood Culture System policy approved by the Laboratory Director on 09/22/22, directed staff to file the Certificate of Conformance that comes in each case of media and to examine a few bottles from each case and document on the "Media QC Log Form." 4. The Media QC Log Form and the Certificates of Conformance for the blood culture media could not be provided when requested at 2:57 p.m. on 12/16/22. 5. In an interview at 3:03 p.m. on 12/16/22, the GS confirmed they are no longer keeping a QC Media Log. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, record review, and an interview with laboratory personnel, the laboratory failed to define and evaluate the acceptable relationship between two Chemistry testing methods at least twice annually in 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:45 a.m. on 12/16/22. 2. The following Chemistry methods for Basic Metabolic Panel (BMP) testing were observed as present and available for use during the tour: Roche Cobas c501 - primary method iSTAT Chem 8+ - back up method 3. A twice annual process for comparison of test

	results obtained from multiple non-waived methods was not found in the laboratory's procedure manual. 4. Comparison of test results obtained from the two Chemistry methods was not found in laboratory records from 2021 and 2022. The laboratory was unable to provide documentation of test comparisons upon request. 5. In an interview at 12:50 p.m. on 12/16/22, GS and Testing Personnel 3 confirmed the laboratory was not evaluating the relationship between the two Chemistry methods at least twice annually. In an interview at 1:36 p.m. on 12/16/22, the GS indicated it was her understanding this regulation was met by performing the twice annual calibration verification on the instruments.