Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404531	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen La Crescent Clinic	226 N Second St, La Crescent, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Hematology proficiency testing (PT) result for 1 analyte in 2019. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:50 p.m. on 07/22/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. The laboratory received an unacceptable Lymphocyte (Lymph) PT result for 1 of 5 PT challenges completed for the 2019 Hematology 3rd event. See below. API 2019 Hematology 3rd event Sample Test Lab result API range HSY-08 Lymph 37.1 22.0-28.3 4. Investigation of unacceptable PT results was required as established in the Quality Assurance for Laboratory Testing procedure provided by the laboratory. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 4:15 p.m. on 07/22/21, the LD confirmed the above finding.
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 procedure evaluation by the Centers for Medicaid and Medicare Services (CMS), the laboratory failed to include adequate step-by-step instructions for the performance and interpretation of a Hematology procedure in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 1:50 p.m. on 07/22/21. 2. A Sysmex KX-21N hematology analyzer and Olympus Zeiss AXID microscope were observed as present and available for use during the tour of the laboratory. The laboratory performed automated complete blood counts and manual differentials as indicated by the TC during the tour. 3. The Differential: Counting and Morphology procedure provided by the laboratory on 07/29/21 was evaluated by CMS on 07/30/21 and found to be inadequate in the following areas : - Clinic Sites and Partner sites were not named or defined - "Exceptionally abnormal RBC morphology with greater than 2+ morphology" was not defined 4. In an email sent at 1:02 p.m. on 08/02/21, the TC and Laboratory Director were notified of this finding. .