Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404587	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Spring Grove Clinic	123 5th Avenue Southeast, Spring Grove, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Hematology proficiency testing (PT) samples from 1 of 5 Hematology PT events reviewed from late 2019 through mid 2021 were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 89:05 a.m. on 07/22/21. 2. The laboratory performed PT in 2019, 2020, 2021 using the American Proficiency Institute (API) proficiency provider. 3. The Quality Assurance for Laboratory Testing procedure provided by the laboratory indicated PT samples would be tested in the same manner as patient specimens. 4. Hematology Blood Cell Identification (BCI) PT samples were tested by multiple testing personnel (TP) prior to the 2020 3rd event submission deadline as indicated on the API Attestation Statement. See below. 2020 - Hematology 3rd event Submission deadline 11/24/20 Samples BCI-11 through BCI-15 Tested by TP1 and TP4 on 11/20/20 5. In an interview at 11:25 a.m. on 07/22/21, the TC 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 9:05 a.m. on 07/22/21. 2. A Sysmex KX-21N hematology analyzer and Olympus BH-21 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 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. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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 2 of 2 reportable ranges obtained during performance verification activities completed in 2020 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:05 a.m. on 07/22/21. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities for Sodium (Na) and Potassium (K) tested on the i-STAT were completed in December

	2020. The laboratory began testing patient specimens using this analyzer on 03/01/21 as indicated by the TC and confirmed by laboratory records. 4. The upper and lower limit of the reportable ranges for Na and K in the Chemistry Testing using the i-STAT EC8+, EG6+, Crea, Chem 8+ Cartridge Types procedure did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte PV Procedure Na 101-178 100-180 K 2.3-7.8 2.0-9.0 5. Na and/or K testing was performed on 28 patient specimens since date of implementation through date of survey, 03/01/21 - 07/22/21, as indicated on a laboratory report provided by the Laboratory Director on 07/22/21. 6. In an interview at 11:45 a.m. on 07/22/21, the TC confirmed the above finding. .