Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2047970	10/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sartell Pediatrics	111 2nd Street South, Sartell, 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 number and type of quality control (QC) materials required each day of testing and corrective action instructions for QC results that fail to meet the laboratory's acceptability criteria for one of two new testing procedures implemented by the laboratory in 2021. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 10/27/22. 2. A Medonic M Series hematology analyzer was observed as present and available for

	use during the tour of the laboratory. The laboratory completed performance verification activities for this analyzer in August 2021 and began performing Complete Blood Counts (CBC's) with Automated Differential testing on 08/30/21 as indicated by TP1 and confirmed in laboratory records. 3. The number and type of QC material used for daily QC was not defined in the Medonic M-Series CBC procedure located in the Lab Procedure Manual. The laboratory was unable to provide written instruction for QC material number and type requirements upon request. 4. Corrective action step-by-step instructions for out of range QC results were not found in the Medonic M-Series CBC procedure. The laboratory was unable to provide written instruction for this activity upon request. 5. The laboratory performed approximately 400 CBC's annually as indicated on the Clinical Laboratory Improvement Amendments Application for Certification provided by the laboratory on 10/27/22. 6. In an interview at 12:50 p.m. on 10/27/22, TP1 confirmed the above 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 two of five reportable ranges obtained during the single Hematology performance verification (PV) activity completed in 2021 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 010/27/22. 2. A Medonic M-Series hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began performing Complete Blood Counts (CBC's) with Automated Differential testing on this analyzer on 08/30/21. 3. PV activities on the Medonic analyzer were completed in August 2021 as indicated in laboratory records found in the Medonic M-Series manual. Five analytes were reviewed for reportable range accuracy as indicated below. WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin PLT - Platelets HCT - Hematocrit 4. The upper reportable range limits adopted by the laboratory for HGB and PLT did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the Medonic M-Series CBC procedure located in the Lab Procedure Manual. The reportable range values found in the procedure were the analytical measuring ranges provided by the manufacturer. See below. Analyte PV Procedure HGB 0.9-22.1 2.0-23.0 PLT 10-900 30-1000 5. The laboratory performed approximately 400 CBC's annually as indicated on the Clinical Laboratory Improvement Amendments Application for Certification provided by the laboratory on 10/27/22. 6. In an interview at 12:50 p.m. on 10/27/22, TP1 confirmed the above finding. .