Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0399870	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Pediatrics	14050 Nicollet Ave Suite 300, Burnsville, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, document review, and interview, with laboratory personnel, the laboratory failed to meet requirements for the specialty of Hematology as specified in 493.1251, 493.1253, 493.1256, and 493.1282. Findings are as follows: 1. The laboratory failed to establish written procedures for staff to follow when flagged values are obtained on patient testing. See D5403 2. The laboratory failed to perform a complete performance verification of the Hematology analyzer prior to putting it into production in May 2022. See D5421 3. The laboratory failed to verify criteria for quality control (QC) material prior to putting it into production for all QC lot changes since May 2022. See D5469 4. The laboratory failed to ensure corrective actions were taken when patient testing resulted with flagged values. See D5781 .
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 establish a written procedure for laboratory staff to follow when patient testing results with flags on analytes ordered by the providers. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory at 1:30 p.m. on August 16, 2023. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. An approved written procedure for laboratory staff to follow when patient testing results with flags, was not found in the laboratory procedure manual. 4. The laboratory was unable to provide a procedure for this process upon request. 5. The laboratory performed approximately 3,909 hematology tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on August 17, 2023. 6. In an interview at 4:15 p.m. on August 16, 2023, the 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 Hematology performance verification (PV) activity completed in May 2022 were adopted by the laboratory. The laboratory also failed to verify the appropriate reference intervals for the laboratory's patient population prior to reporting patient test results in May 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory at 1:30 p.m. on August 16, 2023. 2. A Sysmex XP-300 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 in May 2022. 3. PV activities on the XP-300 analyzer were completed in May 2022, as indicated by laboratory records, found in the Sysmex XP-300 Hematology Analyzer Resource and Validation Manual.

	Five analytes were reviewed for reportable range accuracy as indicated below. WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin HCT - Hematocrit PLT - Platelets 4. The upper reportable range limits adopted by the laboratory for HGB, and HCT did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the Sysmex XP-300 Automated Hematology Analyzer procedure located in the Laboratory Procedure Manual. See below. Analyte PV Procedure HGB 0-22.40 0.1-25.0 g/dL HCT 0.1-59.8 10.0-60.0 % 5. The PV documents provided failed to provide evidence the laboratory had verified the normal ranges (reference intervals) for the laboratory's patient population. 6. The laboratory performed approximately 3,909 hematology tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 7. In an interview at 3: 02 p.m. on August 16, 2023, the TP1 confirmed the above finding. .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the criteria for acceptability for hematology quality control (QC) material for 2022 and 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory at 1:30 p.m. on August 16, 2023. 2. The Sysmex XP-300 Hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Per the laboratory's Sysmex XP-300 Automated Hematology Analyzer procedure, found in the Laboratory Procedure Manual, when starting a new lot of controls the laboratory is to parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production. 4. Documents for all QC lot changes, since the XP-300 was put into production in May 2022, were reviewed on the day of survey, August 16, 2023. Five QC lot changes occurred on the following dates: 07/27/2022, 10/18/2022, 01/04/2023, 04/23/2023, and 06/27/2023. For each of these QC lot changes the laboratory failed to follow their policy and only tested each level of QC one time prior to putting the new lot into production. 5. In an interview at 2:15 p.m. on August 16, 2023, TP1 confirmed the above findings. .
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate 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 corrective actions were taken when patient testing resulted with flagged values on the hematology analyzer. The laboratory performs 3,909 hematology tests annually. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory at 1:30 p.m. on August 16, 2023. 2. The Sysmex XP-300 Hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. All patient who had hematology testing performed in April 2023 and June 2023 were reviewed on the day of survey. 84 patients of the 132 patients with hematology testing performed in April 2023, had at least one flagged value. 78 patients of the 122 patients with hematology testing performed in June 2023, had a t least one flagged value. 4. 15 of the 84 patient test results with multiple flags from April 2023, were pulled for review. The Test Request, instrument print off, and Final Test Report were reviewed. 6 of the 15 had one analyte ordered (HGB) and resulted with no flag on that analyte. 9 of the 15 had a Complete Blood Count (CBC) ordered and had patient test values reported with flagged values without corrective actions being documented. 5. 15 of the 78 patient test results with multiple flags from June 2023, were pulled for review. The Test Request, instrument print off, and Final Test Report were reviewed. 10 of the 15 had one analyte ordered (HGB) and resulted with no flag on that analyte. 5 of the 15 had a CBC ordered and had patient test values reported with flagged values without corrective actions being documented. 6. The laboratory was unable to provide the missing corrective action records upon request. 7. In an interview at 4:03 p.m. on August 16, 2023, TP1 and the Operations Manager confirmed the above findings.