Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0964852	08/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Pediatrics	1515 St Francis Ave, Suite 100, Shakopee, 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, 493.1256, 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 verify criteria for quality control (QC) material prior to putting it into production for all QC lot changes since May 2022. See D5469 3. 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 10:20 a.m. on August 17, 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 2,600 hematology tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 6. In an interview at 10:45 a.m. on August 17, 2023, TP1 confirmed the above finding. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document function checks for 1 of 1 centrifuges and 1 of 1 microscope in 2022. Findings are as follows: 1. The laboratory performed non-waived testing under the specialties of Microbiology, Chemistry, and Hematology testing as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory at 10:20 a.m. on August 17, 2023. 2. A PSS 602 Select urine and blood centrifuge and a Olympus CX31 microscope were observed as present and available for use in the laboratory during the tour. TP1 stated that BME Lab and Science perform the function checks on the centrifuge and the microscope in an interview during the tour of the laboratory. 3. The laboratory's Equipment Maintenance procedure, found in the black three ringed Laboratory Procedure Manual, indicated the centrifuges tachometer and timer functions were verified yearly by BME and the microscope optics, illumination system, and mechanical functions should be verified yearly by BME. 4. Review of service documents from BME Lab and Science found

	the centrifuge and the microscope were last serviced and had function checks performed on February 9, 2023. 5. Documentation of 2022 laboratory centrifuge and microscope function checks was not found during review of laboratory records and could not be provided at request. Documentation was found for function check performance on the microscope and centrifuge in 2021, performed by another company. 6. During an interview at 11:37 a.m. on August 17, 2023, TP1 confirmed the laboratory did not have any documentation of function checks performed on the centrifuge or the microscope for 2022. .
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 10:20 a.m. on August 17, 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 17, 2023. Five QC lot changes occurred on the following dates: 07/29/2022, 10/20/2022, 01/11/2023, 04/06/2023, and 06/24/2023. 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 10:45 a..m. on August 17, 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 2.600 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 10:20 a.m. on August 17, 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 May 2023 and June 2023 were reviewed on the day of survey. 36 patients of the 96 patients with hematology testing performed in May 2023, had at least one flagged value. 42 patients of the 101 patients with hematology testing performed in June 2023, had a t least one flagged value. 4. 9 of the 36 patient test results with multiple flags from May 2023, were pulled for review. The Test Request, instrument print off, and Final Test Report were reviewed. 5 of the 9 had one analyte ordered (HGB) and resulted with no flag on that analyte. 3 of the 9 had a Complete Blood Count (CBC) ordered and had patient test values reported with flagged values without corrective actions being documented. One (1) of the 9 had a CBC ordered with corrective actions written on the instrument print off and in the electronic medical record. 5. 8 of the 42 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. 7 of the 8 had one analyte ordered (HGB) and resulted with no flag on that analyte. 1 of the 8 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 11:40 a.m. on August 17, 2023, TP1 and the Operations Manager confirmed the above findings. .