Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403169	08/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Pediatrics	3400 W 66th St Suite 450, Edina, 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, 493.1254, 493.1256, 493.1282 and 493.1291. 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 perform and document required maintenance on a Hematology analyzer during five month in 2023. See D5429 4. 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 5. The laboratory failed to ensure corrective actions were taken when patient testing resulted with flagged values. See D5781 6 The laboratory failed to ensure the correct test location was listed on the Final Test Reports since the laboratory moved in May 2023. See D5805 .
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 11:25 a.m. on August 15, 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 3,405 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 3:00 p.m. on August 15, 2023, the Operations Manager and 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 11:25 a.m. on August 15, 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 0-21.90 0.1-25.0 g/dL HCT 0.1-59.2 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 3,405 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 1: 38 p.m. on August 15, 2023, the Operations Manager confirmed the above finding. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. 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 required maintenance at the frequency required for one of one Hematology analyzer in during five months in 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 11:25 a.m. on August 15, 2023. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Manufacturer maintenance requirements for the Sysmex XP-300 analyzer were established in the Sysmex XP-300 Automated Hematology Analyzer procedure, located in the Laboratory Procedure Manual. The maintenance requirements were also found on the instrument maintenance logs. 4. Documentation of the daily maintenance performed on the XP-300 was not found for 9 of 153 days reviewed on the March, April, May, June, and July 2023 instrument maintenance logs. The following dates were missing documented daily maintenance: March 24, 2023 May 25, 26, 29 and 30, 2023 July 4, 6, 19 and 20, 2023 5. Documentation of the weekly maintenance performed on the XP-300 was not found for 12 of 21 weeks reviewed on the March, April, May, June, and July 2023 instrument maintenance logs. The following weeks were missing weekly maintenance: March 6, 2023 March 13, 2023 March 20, 2023 March 27, 2023 April 24, 2023 May 8, 2023 May 22, 2023 May 29, 2023 June 12, 2023 July 10, 2023 July 17, 2023 July 24, 2023 6. Documentation of the monthly maintenance performed on the XP-300 was not found for three of five months reviewed on the March, April, May, June, and July 2023 instrument maintenance logs. The following months were missing monthly maintenance: April 2023 May 2023 June 2023 7. In an interview at 12:55 p.m. on August 15, 2023, TP1 confirmed the above findings. .
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 2 of 2 centrifuges and 1 of 1 microscope in 2021 and 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 11:25 a.m. on August 15, 2023. 2. A Select Medical C856 urine centrifuge, a Horizon Mini E 642E blood centrifuge and an American Optical 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 two centrifuges and the one microscope in an interview during the tour of the laboratory. 3. The laboratory's Equipment Maintenance procedure, found in the teal three ringed Laboratory Procedure Manual, indicated the centrifuges tachometer and timer functions were verified every 6 months by Children's. and the microscope optics, illumination system, and mechanical functions should be verified yearly by Children's. 4. Review of service documents from BME Lab and Science found the two centrifuges and the microscope were last serviced and had function checks performed on February 8, 2023. 5. Documentation of 2021 and 2022 laboratory centrifuge and microscope function checks was not found during review of laboratory records and could not be provided at request. 6. During an interview at 1:30 p.m. on August 15, 2023, the Operations Manager (OM) confirmed the laboratory did not have any documentation of function checks performed on the two centrifuges or the microscope for 2021 or 2022. The OM further clarified that the laboratory had transitioned from Children's performing the function checks in 2021 to BME Lab and Science and that there was a lapse in the function checks getting done at the appropriate timeframes during the transition. .
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 on August 15, 2023, at 11:25 a.m. 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 15, 2023. Four QC lot changes occurred on the following dates:10/17/2022, 01/10/2023, 03/31/2023, 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 2:45 p.m. on August 15, 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 3,405 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 on August 15, 2023, at 11:25 a.m. 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 March 2023 and July 2023 were reviewed on the day of survey. 83 patients of the 125 patients with hematology testing performed in March 2023, had at least one flagged value. 78 patients of the 149 patients with hematology testing performed in July 2023, had a t least one flagged value. 4. 10 of the 83 patient test results with multiple flags from March 2023, were pulled for review. The Test Request, instrument print off, and Final Test Report were reviewed. 8 of the 10 had one analyte ordered (HGB) and resulted with no flag on that analyte. 2 of the 10 had a Complete Blood Count (CBC) ordered

	and had patient test values reported with flagged values without corrective actions being documented. 5. 17 of the 78 patient test results with multiple flags from July 2023, were pulled for review. The Test Request, instrument print off, and Final Test Report were reviewed. 16 of the 17 had one analyte ordered (HGB) and resulted with no flag on that analyte. 1 of the 17 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 3:45 p.m. on August 15, 2023, TP1 and the Operations Manager confirmed the above findings. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure all test result reports included the address of the laboratory location. Findings are as follows: 1. The laboratory performed non-waived testing under the specialties of Bacteriology, Chemistry, and Hematology as confirmed by Testing Personnel #1 (TP1) during a tour of the laboratory on August 15, 2023, at 11:25 a.m. 2. The laboratory moved locations in May 2023, from an old location (6517 Drew Ave S, Edina, MN 55435) to the current location (3400 W 66th St. Suite 450, Edina, MN 55435). 3. All final test reports reviewed since the move in May 2023, to the date of the on-site survey had the incorrect, old laboratory address listed. 17 patient final test reports were reviewed the day of survey, all from July 2023. All 17 final test reports had the old laboratory address listed as the testing location. 4. The estimated annual test volume was 4,134 as indicated on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 obtained during the survey. 5. In an interview at 2:45 p.m. on August 15, 2023, TP1 and the Operations Manager confirmed the above findings. .
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on review of personnel records and interview with laboratory personnel, the laboratory failed to ensure staff performing moderately complex testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: Documentation was

	not provided for three of four testing personnel showing educational requirements under 493.1423 were met. See D6065. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure three of four testing personnel had the required educational credentials to perform moderate complexity testing. Findings are as follows: 1. The laboratory performed moderately complex testing in Bacteriology, Chemistry and Hematology as confirmed Testing Personnel 1 (TP1) during a tour of the laboratory at 11:25 a.m. on August 15, 2023. 2. Educational documents were not found for Testing Personnel #2 (TP2), Testing Personnel #3 (TP3), or Testing Personnel #4 (TP4) during a review of personnel records. 3. Survey document Form CMS-209 (Laboratory Personnel Report (CLIA)), signed by the Laboratory Director (LD) on August 15, 2023, listed TP2, TP3, and TP4 as qualified to perform moderate complexity testing. 4. In an interview at 1:45 p.m. on August 15, 2023, the TP1 and the Operations Manager confirmed educational documents were missing for the three testing personnel. 5. Survey document Form CMS-116 (Clinical Laboratory Improvement Amendments (CLIA) Application for Certification), signed by the LD on August 15, 2023, estimated an annual test volume of 4,134. .