Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0964852	07/11/2025
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
D0000	. The Metropolitan Pediatrics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on July 8, 2025. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1291 Test report .
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) (a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure annual competency assessment records were retained for at least two years in 2023 and 2024. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 10:04 a.m. on 7/8/25. 2. Previously qualified Testing Personnel 1, 2, and 3 (TP1, TP2. TP3) performed moderate complexity Chemistry and Hematology testing in 2023 and 2024 as indicated on the Laboratory Personal Report (CLIA) Form CMS-209 provided by the laboratory on the date of survey. 3. Annual 2023 competency assessment documents for TP1, TP2, and TP3 were not found during review of laboratory personnel records. The laboratory was unable to provide the missing documents upon request as confirmed by the LS in an email received at 11:55 a.m. on 7/11/25. .
D5805	TEST REPORT CFR(s): 493.1291(c) (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 reports included the address of the laboratory in 2024 and 2025. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 10:04 a.m. on 7/8/25. 2. Three laboratory reports from 2024 and 2025 reviewed during the survey included the address of a different Metropolitan Pediatrics location. See below. Laboratory address: 1515 St Francis Ave, Suite 100, Shakopee, MN 55379 Address on patient reports: 3400 West 66th Street, Suite 450, Edina, MN 55435-2115 3. The laboratory performed 3190 tests annually as indicated on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 provided by the laboratory on the date of survey. 4. In an interview at 12:44 p.m. on 7/8/25, the Technical Consultant confirmed the above findings. .
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with the laboratory personnel, the laboratory failed to ensure two of ten Urinalysis reference intervals reviewed were consistent between the procedure and a patient test report in 2024. Findings are as follows: 1. The laboratory performed Urinalysis testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 10:04 a.m. on 7/8 /25. 2. An Olympus CX31 microscope was observed as present and available for use for urine microscopic exams during the tour. 3. Urine microscopic exam reference intervals defined in the Urinalysis - Microscopic Evaluation procedure provided by the laboratory were not consistent with urine microscopic exam reference intervals included on a patient test report from 7/19/24. See below. Procedure Patient Report WBC Female 0-5/hpf WBC 0-0/hpf RBC Female 0-4/hpf RBC 0-0/hpf 4. The LS indicated the laboratory performed 529 urine microscopic examinations annually, and confirmed the above findings in an interview at 12:44 p.m. on 7/8/25. .