

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399870	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Metropolitan Pediatrics	Street Address, City, State 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
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 23, 2024. The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1407 Laboratory director responsibilities 493.1413 Technical consultant responsibilities .
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two non-waived testing procedures included all required elements. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 07/23/24. 2. An American Optical 150 microscope was observed as present and available for use during the tour: The laboratory performed Urine Sediment microscopic examinations (USed) using this instrument. 3. USed reporting criteria and reference ranges for microscopic elements were not established in the Urinalysis Procedure found in the Laboratory Procedure Manual. 4. In an interview at 1:00 p.m. on 07/23/24, TP1 confirmed the above finding. .</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure two of six testing personnel (TP) were assessed semi-annually and annually through testing previously analyzed specimens, blind samples, or proficiency testing (PT) samples for one of two tests performed in 2022 and 2023. Findings are as follows: 1. The laboratory was cited for non-performance of blind sample assessment during the previous survey conducted on 07/19/22. 2. Blind sample assessment for Urine Sediment microscopic examinations was not found on date of current survey, 07/23/24, for two of six testing personnel in 2022 and 2023 laboratory records. See D6051. 3. In an interview on 07/23/24 at 11:50 a.m., Testing Personnel 1 confirmed the above finding. .

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure competency assessments were completed by qualified personnel in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 07/23/24. 2. The following instruments were observed as present and available for use during the tour: Hematology -Sysmex XP-300 (used for complete blood counts) Chemistry -American Optical 150 microscope (used for Urine Sediment microscopic examination) 3. Performance of competency assessments was required by the Technical Consultant as established in the Laboratory Personnel Competency Testing Policy found in the Laboratory Procedure Manual. 4. 2022, 2023. and 2024 competency assessment documents reviewed for six of six testing personnel were performed by personnel who did not meet the Technical Consultant education requirements at 42 CFR 493.1411. 5. In an interview at 11:50 a.m. on 07/23/24, TP1 confirmed the above finding. .

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure two of six testing personnel (TP) were assessed semi-annually and annually through testing previously analyzed specimens, blind samples, or proficiency testing (PT) samples for one of two moderate complexity tests performed in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 07/23/24. 2. An American Optical 150 microscope was observed as present and available for use during the tour: The laboratory performed Urine Sediment microscopic examinations (USed) using this instrument. 3. Assessment of test performance using external proficiency samples was required at least annually for all TP as established in the Proficiency Testing procedure found in the Laboratory Procedure Manual. 4. Testing Personnel 3 (TP3) did not participate in USed PT in 2022 and 2023 for annual competency assessment and Testing Personnel 6 (TP6) did not participate in USed PT in 2023 for semi-annual assessment as indicated on American Proficiency Institute Attestation Statements reviewed on date of survey. 5. The laboratory was unable to provide alternative blind sample evaluation documentation completed in 2022 and 2023 for TP3 and TP6 upon request. 6. In an interview at 11:50 a.m. on 07/23/24, TP1 confirmed the above finding. *This finding was previously cited during the 07/19/22 survey* .