

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399870	(X3) Date Survey Completed 09/30/2020
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Bacteriology, Urinalysis, and Hematology proficiency testing samples were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Bacteriology, Urinalysis, and Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) proficiency provider. 3. An untitled document located in the PT manual indicated all PT samples would not be performed by one employee. 4. The attestation statements for all API PT events from the third events of 2018 through the second events of 2020 indicated multiple testing personnel completed testing on each PT sample. 5. In an interview at 12:15 p.m., TP1 confirmed the above finding and indicated the PT samples were tested by two employees in an effort to verify test result. .</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2019 proficiency testing (PT) score when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed manual microscopic analysis of urine sediment testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One urine sediment result from the first 2019 Hematology PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte US-02 Urine Sediment 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. In an interview at 12:20 p.m. on 09/30/20, TP1 confirmed the above finding. .

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the laboratory failed to follow an established policy to verify the accuracy of test results manually entered into the electronic medical record. Findings are as follows: 1. The laboratory performed Bacteriology, Urinalysis, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. TP1 indicated the test results were entered manually into NextGen, the electronic medical record. 2. A requirement for review of 10 manual entries per quarter was established in the Test Result Reporting Review procedure located in the CLIA Manual. 3. Documentation of manual test result entry review from the second quarter of 2018 through date of survey was not found in laboratory records. The laboratory was unable to provide the missing documentation for this time period upon request. 4. In an interview at 11:15 a.m. on 09/30/20, TP1 confirmed the above finding. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure training for 1 of 1 new testing personnel was performed and documented in 2018. Findings are as follows: 1. The laboratory performed Bacteriology, Urinalysis, and Hematology testing as confirmed by Testing Personnel

1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. 2. Testing Personnel 5 (TP5) was hired on 09/18/18 as indicated on the competency assessment form completed in September 2019. 3. Initial training documents for TP5 were not found during review of laboratory's records. 4. The laboratory was unable to provide the missing documents upon request. 5. In an interview at 11:10 a.m., TP1 confirmed the above finding and indicated TP5 began patient testing soon after hire in 2018. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 1 of 1 testing personnel hired in 2018. Findings are as follows: 1. The laboratory performed Bacteriology, Urinalysis, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. 2. The Personnel Competency Testing Policy procedure located in the CLIA manual indicated personnel were evaluated semi-annually during the first year of employment and annually thereafter. 3. Testing Personnel 5 (TP5) was hired on 09/18/18 as indicated on the competency assessment form completed in September 2019. Initial training documents from 2018 were not found during review of laboratory records. See D6045. 4. A semiannual competency assessment for TP5 was not found in laboratory records. 5. The laboratory was unable to provide the missing semi-annual competency documents upon request. 6. In an interview at 11:10 a.m. on 09/02/20, TP1 confirmed the above finding and indicated TP5 began patient testing soon after hire in 2018. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure a comprehensive annual competency assessment was performed for 2 of 4 testing personnel in 2018. Findings are as follows: 1. The laboratory performed Bacteriology, Urinalysis, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/30/20. 2. The Personnel Competency Testing Policy procedure located in the CLIA manual indicated personnel were evaluated semi-annually during the first year of employment and annually thereafter. 3. The 2018 annual competency assessments for Testing Personnel 2 and Testing Personnel 3 did not include an evaluation of Throat Cultures, Urine Cultures, and Hematology testing. 4. The laboratory was unable to provide the missing annual competency assessments upon request. 5. In an interview at 11:13 a.m. on 09/30/20, TP1 confirmed the above finding.