

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0964852	(X3) Date Survey Completed 05/25/2023
Name of Provider or Supplier Metropolitan Pediatrics	Street Address, City, State 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
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure hematology proficiency testing (PT) samples were tested consistent with the number of times the laboratory routinely tested patient samples from one of six PT events in 2021, 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 1:13 p.m. on May 25, 2023. TP1 confirmed the observed Sysmex XP-300 hematology analyzer replaced the Beckman Coulter ACT-Diff in May 2022. 2. The laboratory performed PT for Hematology using the American Proficiency Institute (API) PT provider. 3. PT test result printouts, generated by the Beckman Coulter ACT Diff analyzer, confirmed the five PT samples from the API 2021 Hematology/Coagulation 3rd Event were tested two times on November 22, 2021. See below for run times. Sample 1st run 2nd run 11-22-21 11-22-21 HEM-11 15:29 15:31 HEM -12 15:46 15:50 HEM -13 15:51 15:55 HEM -14 15:58 16:02 HEM -15 16:03 16:07 4. In an interview at 2:37 p.m. on May 25, 2023, the Operations Manager and TP1 confirmed the above findings. .</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency</p>

testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to retain a copy of proficiency testing records from two of six proficiency testing (PT) events reviewed in 2021, 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 1:13 p.m. on May 25, 2023. 2. The laboratory performed PT for Hematology using the American Proficiency Institute (API) PT provider. 3. The following elements of PT records could not be located during the survey: Year: 2022 PT Series Hematology/Coagulation Event: 1st Event Item(s): Proficiency Testing Performance Evaluation Year: 2021 PT Series Hematology /Coagulation Event: 3rd Event Item(s): Instrument printouts matching values submitted to API 4. The laboratory was unable to provide the missing documents at request the day of survey. 5. In interviews between 2:30 p.m. and 3:20 p.m. on May 25, 2023, TP1 and the Operations Manager confirmed the above finding. .

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Laboratory Director (LD) failed to review and evaluate proficiency testing (PT) results on two of six Hematology/Coagulation events in 2021, 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 1:13 p.m. on May 25, 2023. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The LD's review and evaluation of test results was required for all PT events as indicated on the Proficiency Testing Performance Evaluation Form found with each event of API performed by the laboratory. 4. The LD failed to review and evaluate test results for two of six API PT events from 2021, 2022 and 2023. See below. Event Specialty missing LD review 2022-1 Hematology/Coagulation 2021-2 Hematology/Coagulation 5. In an interview at 3:15 p.m. on May 25, 2023, TP1 confirmed the above finding. .