| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 24D0964852 | 05/07/2019 |
| **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 |
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| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to ensure microscopic examination proficiency testing (PT) was performed consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Pinworm and Urine Sediment microscopic examination testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m. on 05/07/19. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. Microscopic examination PT for Pinworms and Urine Sediment from the API 2017 Hematology/Coagulation 3rd event and the API 2018 Hematology/Coagulation 1st event were completed by multiple testing personnel as indicated on API Attestation Statements. See below. Event Testing personnel (TP) 2017-3 TP6, former TP C.P. 2018-1 TP3, former TP T.P. 4. In an interview at 12:30 p.m. on 05/07/19, the LS confirmed the PT had been performed by multiple testing personnel prior to the submission date and patient specimens would not routinely be handled in this manner. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, laboratory personnel failed to follow 1 of 1 Individual Quality Control Plans (IQCP) for Urine Culture quality control performance. Findings are as follows: 1. The laboratory performed Urine Culture testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m. on 05/07/19. 2. Urine Culture quality control (QC) frequency requirements were established as weekly and with new lots and shipments of media in the Metropolitan Pediatrics Individual Quality Control Plan. 3. Weekly QC was not performed or documented after 02/18/18 as indicated on the Quality Control for Urine Culture Plates forms revieweed on date of survey. 4. Thirty four patients received Urine Culture testing results which were reported without weekly QC performance in the timeframe reviewed; December 2018 through January 2019. The QC dates documented on the Quality Control for Urine Culture Plates form were 11/27/18, 01/10/19, and 02/14/19. Laboratory patient testing records indicated 20 patient specimens in December 2018 and 14 patient specimens in January 2019 received Urine Culture testing without weekly QC performance. 5. In an interview at 1:40 p.m. on 05/07/19, the LS confirmed the above finding and explained the laboratory changed their QC process but had not updated the IQCP. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to follow the Quality Assessment Plan (QAP) for 1 of 1 Individualized Quality Control Plans (IQCP) developed by the laboratory. Findings are as follows: 1. The laboratory performed Urine Culture testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m. on 05/07/19. 2. The laboratory implemented an IQCP on 11/01/16 to reduce quality control requirements for Urine Cultures. The QAP indicated the IQCP would be reviewed annually. 3. Annual IQCP review documentation was not present in laboratory records. The laboratory was unable to provide documentation of IQCP quality assessment review from 2017 and 2018 upon request. 4. In an interview at 2:05 p.m. on 05/07/19, the LS confirmed the above finding. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to evaluate 1 of 7 testing personnel for competency in moderate |

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| | complexity test procedures in 2018 and 2019 . Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m on 05/07 /19. 2. Personnel record review indicated the LS was evaluated for competency in 2018 and 2019 by Testing Personnel 1 (TP1). 3. TP1 was not qualified to perform the competency evaluation as her highest level of education was a high school diploma. The laboratory was unable to provide competency evaluation documents completed by a qualified TC in 2018 and 2019 upon request. 4. In an interview at 10:45 a.m. on 05/07/19, the LS confirmed the above finding. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure 4 of 4 testing personnel were assessed through testing Microbiology, Chemistry,and Hematology previously analyzed specimens, blind samples, or proficiency testing samples at least annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Pinworm (PW) and Urine Sediment (US) microscopic examinations, Throat Cultures (TC), and Complete Blood Count (CBC) testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m on 05/07/19. 2. Proficiency testing (PT) results for were being used to evaluate testing personnel competency as established in the laboratory's Competency Assessment Policy. 3. Laboratory records indicated all testing personnel did not perform PT for each non-waived test in 2017 and 2018. The laboratory was unable to provide additional documented evaluations of blind sample testing upon request. See below where "x" indicates proficiency testing was not performed. 2017 Testing Personnel (TP) LS TP1 TP2 TP3 PW x x US x x x TC x x CBC x x x 2018 Testing Personnel LS TP1 TP2 TP3 PW x US x TC x CBC x x 4. In an interview at 2:10 p.m. on 05/07/19, the LS verified the testing personnel routinely performed the non-waived testing and confirmed PT for this testing was not completed by all staff in 2017 and 2018 as indicated above. |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the technical consultant failed to ensure 1 of 1 testing personnel received documented training when newly hired. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Laboratory Supervisor (LS) during a tour of the laboratory at 9:20 a.m on 05/07/19. 2. Testing personnel 7 (TP7), listed on the Laboratory Personnel Report (CLIA) Form CMS-209, began working in the laboratory on 10/15/18 as indicated in laboratory personnel |

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| | records. TP7 met the qualifications to perform moderate complexity testing at 493.1423(b)(4) based on a review of education documents. 3. Training documents for TP7 were not found during a review of laboratory records. The laboratory was unable to provide these documents upon request. 4. In an interview at 10:45 a.m. on 05/07 /19, the LS confirmed the above finding and stated training had been completed for TP7 but the training was not documented. |