| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2095956 | 05/21/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pm Pediatrics Of Greenbelt | 7401 Greenbelt Road, Greenbelt, MD | |

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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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(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 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory did not ensure that the testing person who performed the test initialed the instrument printouts with the PT samples' test results in the same manner at the patients. Findings: 1. The PT records from 2016 and 2017 (6 events) were reviewed. The instrument printouts with the PT results did not include the initials of the person who performed the test in the same manner as the patients. 2. The attestation worksheet for event M-1 of 2018 listed 3 different testing personnel signatures; event M-3 of 2017 listed 4 different testing personnel signatures; events M-2 and M-1 of 2017 listed 2 different testing personnel signatures; event M-3 of 2016 listed 3 different testing personnel signatures; and event M-2 of 2016 listed 2 different testing personnel signatures. 3. The attestation worksheets had multiple signatures and the instrument printouts had no signatures. There was no way to determine who performed each of the PT specimens. 4. During the survey on 05/21/2018 at 12:30 PM the laboratory supervisor confirmed that the PT worksheets did not include the initials of the testing person who performed the test as required. |

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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the medical assistant, the laboratory did not establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9). Findings: 1. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable; specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 2. Evaluations must be performed at six months and annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 3. During the survey on 05/21/2018 at 12:30 PM the laboratory supervisor confirmed that the policies and procedure manual did not include a written training program along with worksheets for the documentation of the training of the testing personnel and medical assistants who perform pre-analytical and analytical preparation. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the Quality Control (QC) procedure and interview with the laboratory supervisor, the laboratory director did not ensure that the established QC procedure to monitor the overall operation of the laboratory was maintained. Findings: 1. The laboratory's QC procedure requires the laboratory director or qualified designee to conduct the review the QC results on a monthly basis. 2. Review of the laboratory's QC records for 2016 through 2018 show that the monthly QC review was |

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| | being performed by the laboratory supervisor. The laboratory supervisor is not listed as the qualified technical consultant and is not identified as the qualified designee. The review of the QC records is not listed as one of the duties and responsibilities of the laboratory supervisor. 3. During the survey on 05/21/2018 at 12:30 PM the laboratory supervisor confirmed that the laboratory director was not performing the review of the QC review and was not reviewing the data assembled by the laboratory supervisor. II. Based on review of the Quality Assurance (QA) Plan, and Calendar of QA Reviews, and interview with the laboratory supervisor, the laboratory director did not ensure that the established QA procedures to monitor the overall operation of the laboratory were maintained. Findings: 1. The laboratory's written QA plan states that "All QA's to be reviewed and signed by the laboratory director after completion." 2. The QA documents from April 2016 through April 2018 were reviewed. The QA documents included the Quarterly Reviews; "QC - QA Tracking Sheet"; "Monthly Chart Audit QA Tracking Sheet"; "Laboratory QA Review"; "Lab QA - General Form"; and "System/Process Reviewed: Temperature and Humidity Maintenance." None of the documents showed evidence of being reviewed and signed by the laboratory director. 3. The Calendar of QA Reviews lists additional activities to be completed monthly. These activities are to be performed by the qualified technical consultant. The laboratory supervisor, who is not the qualified technical consultant, stated that she completes these activities each month and gives them to the laboratory director for review and signature each month. These documents did not include the documented review of the laboratory director. 4. During the survey on 05/21/2018 at 12:30 PM the laboratory supervisor confirmed that the QA documentation was not reviewed and signed by the laboratory director as required by the laboratory's QA plan. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: The testing personnel confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the laboratory director, clinical consultant, technical consultant and testing personnel. |
| **D6070** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(1) |

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| | Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the procedure manual, review of proficiency testing records, and interview with the laboratory supervisor, the testing person did not follow the laboratory's procedures for initialing instrument printouts. Cross refer to D2015 |