| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0921010 | 09/04/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Woodstock Pediatric Medicine Pc | 2000 Professional Way #200, Woodstock, GA | |

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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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 4, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the laboratory test workload as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD failed to sign the attestation statements for the following Hematology/Coagulation PT events: 2016 -- Event 3; 2017 -- Event 3. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 p.m. confirmed the LD did not sign the attestation statements for the aforementioned PT events. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a six-procedure competency policy and procedure for initial, six month, and annual employee competencies. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 p.m. confirmed the laboratory failed to establish and follow a six-procedure policy and procedure for evaluating laboratory personnel. |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow a written policy to perform proficiency testing (PT) as required. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a policy and procedure for performing PT. 2. SOP review revealed the laboratory failed to establish and follow a policy and procedure for record retention. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom confirmed the SOP did not contain a policy and procedure for PT or for record retention. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. |

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| | This STANDARD is not met as evidenced by:<br>Based on hematology calibration document review and staff interview, the laboratory failed to perform instrument calibrations every six months as required. Findings include: 1. Horiba Micros 60 hematology calibration document revealed the laboratory failed to perform instrument calibrations between 11/12/16 and 11/2/17. There was also no documentation of an instrument calibration performed between 11/2 /17 and the time of survey. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 12:15 p.m. confirmed Horiba Micros 60 hematology analyzer calibrations were not performed during the aforementioned gaps in 2017 and 2018 thus far. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) document review and staff interview, the laboratory failed to perform QC in bacteriology as required. Findings include: 1. QC document review revealed the laboratory failed to perform QC for the Taxo discs and bacteriology media for 2017 and 2018 thus far. 2. QC document review revealed the laboratory failed to perform an incubated sterility check for the bacteriology media for 2017 and 2018 thus far.. 3. An interview with Staff #1 (CMS 209) in the breakroom on 9/4/18 at approximately 3:30 p.m. confirmed the aforementioned QC was not performed for 2017 and 2018 thus far. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of proficiency test (PT) document, testing personnel (TP documents), policy and procedure manual (SOP) review, and staff interview, the laboratory director failed to provide overall managment and direction of the laboratory as required. Findings include: Refer to D2009, D5477, D D6004, D6018, D6019, D6029, and D6032 |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<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 |

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| | test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to delegate the duties of the technical consultant to qualified personnel. Findings include: 1. TP document review revealed the 2016 annual competencies were performed by unqualified TP for the following TP: Staff #s (CMS 209) -- 3, 4, 5, 6, 7, 8, and 9. 2. TP document review revealed the 2017 annual competencies were performed by unqualified TP for the following TP: Staff #s (CMS 209) -- 3, 4, 6, 7, 8, 9 and 10. 3. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom confirmed competencies for the aforementioned TP were performed by unqualified TP. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<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)(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to review PT reports as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the LD failed to review the 2018 Hematology/Coagulation PT report for Event 1. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 p.m. confirmed the LD failed to review the aforementioned PT report. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory |

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| | director (LD) failed to ensure an approved corrective action plan was followed when PT results were found to be unacceptable or unsatisfactory. Findings include: 1. American Proficiency Institute (API) PT document review revealed the laboratory did not perform corrective action for a score of 80 percent for Event 3 -- Hematology /Coagulation 2017 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 p.m. confirmed corrective action was not performed for the aforementioned PT event. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document and staff interview, the laboratory director (LD) failed to ensure the TP received appropriate training for the type of complexity of services offered and that they can perform all testing operations reliably. Findings include: 1. TP document review revealed initial competencies were not performed for Staff #10 (CMS 209) in 2017 and for Staff #2 and Staff #13 (CMS 209) in 2018. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3: 30 p.m. confirmed initial competencies were not performed for the aforementioned TP. |
| **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>The laboratory director (LD) failed to specify in writing the duties and responsibilities of each person and consultant engaged in the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. The LD failed to establish a policy and procedure for the duties and responsibilities of the LD, technical consultant (TC), clinical consultant (CC), and testing personnel (TP) employed in the laboratory. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 |

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| | p.m. confirmed the LD did not establish a policy and procedure for the duties and responsibilities of the LD, TC, CC, and TP. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on TP competency reviews and staff interview, the technical consultant (TC) failed to perform TP annual competencies as required. Findings include: Refer to D6054 |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform a semiannual TP competency as required. Findings include: 1. TP document review revealed the TC failed to perform a semiannual competency on Staff #11 (CMS 209) in 2018. 2. An interview with Staff #1 (CMS 209) on 9/4/18 at approximately 3:30 p.m. in the breakroom confirmed the TC did not perform the semiannual competency on Staff #11 (CMS 209) in 2018. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on TP competency reviews and staff interview, the technical consultant (TC) failed to perform TP annual competencies as required. Findings include: 1. TP competency document review revealed the TC did not perform 2017 annual competencies for the following Staff #s (CMS 209) -- 3, 4, 6, 7, 8, and 9. 2. An interview with Staff #1 (CMS 209) on 9/4/18 in the breakroom at approximately 3:30 p.m. confirmed the 2017 annual competencies for the aforementioned TP were not performed by the TC. This is a repeat deficiency. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>The laboratory must have a sufficient number of individuals who meet the |

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| | qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview, the laboratory failed to hire qualified TP due to lack of education documentation. Findings include:<br>Refer to D6065 |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview, the laboratory failed to hire qualified TP due to lack of education documentation. Findings include:<br>1. TP document review revealed the laboratory failed to provide education documents at the time of survey for the following Staff #s (CMS 209): 2, 5, and 13. 2. An interview with Staff #1 (CMS 209) in the breakroom on 9/4/18 at approximately 3:30 p.m. confirmed education documents were not available for the aforementioned TP at the time of survey. This is a repeat deficiency. |