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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D0904344         | <b>(X3) Date Survey Completed</b><br><br>04/11/2018 |
| <b>Name of Provider or Supplier</b><br><br>Northwest Physicians Associates Pc  | <b>Street Address, City, State</b><br><br>1012 Water Street Suite 8, Meadville, PA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5403</b>              | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on personnel interview of the Laboratory Testing Personnel, Laboratory Operations Manager, and review of the Hematology Procedure Manual on the date of the Complaint Investigation (04/11/2018), the Laboratory failed to have a written procedure for details specific to the laboratory's patient test result reporting practices. Findings include: 1. The written Hematology Procedure Manual did not include requirement 493.1251(b) 13. 2. At the time of the complaint investigation(14:30 04/11 /2018) a policy for manual white blood cell differential turn around times, was not available. 3. On the date of the inspection (04/11/2018), the Laboratory Personnel</p> |

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|                     | <p>confirmed the above findings. 4.. Review of 15 specimen log pages from February 2019 through March 2018 revealed various reporting times since collection. 269 specimens were examined and reported for manual white blood cell differential between 02/01/2018 through 03/31/2018. 64 specimens were examined and reported beyond 24 hours after collection. 10 specimens of the 64 were examined and reported beyond 10 days after collection.</p>  |
| <p><b>D5417</b></p> | <p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br/>CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor observation and interview with the Laboratory Operations Manager and Laboratory Testing Personnel, at the time of the Complaint Investigation (14:30 04/11/2018), the laboratory failed to ensure that 5 of 5 sleeves of Health Link TSA 5 % SB/Maconkey Agar Biplates, had not exceeded their expiration date. Findings include: 1. One open sleeve and 4 unopened sleeves of Health Link TSA 5 % SB/Maconkey Agar BiPlates Lot 1731202 with an expiration date of 02/14/2018, were found in the laboratory refrigerator, while conducting a laboratory walk through. 2. On the date of Complaint Investigation (04/11/2018), the Laboratory Operations Manager confirmed the plates were expired.</p> |
| <p><b>D5429</b></p> | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on interview with the Laboratory Testing Personnel and review of the hematology maintenance records at the time of the Complaint Investigation (14:30 04 /11/2018), the laboratory failed to document monthly maintenance for the Horiba ABX Pentra XL analyzer. Findings include: 1. There was no documentation of monthly concentrated cleaning for the month of March 2018, as required by the manufacturer, for the Horiba ABX Pentra XL analyzer. 2. On the date the Complaint Investigation Investigation(04/11/2018), the Laboratory Testing Personnel confirmed the above findings.</p>   |
| <p><b>D6021</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(5)</p> <p>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>   |

This STANDARD is not met as evidenced by:  
 Based on interview of the Laboratory Testing Personnel and review of the Laboratory Maintenance Records, at the time of the Complaint Investigation (14:30 04/11/2018), the Laboratory Director failed to ensure quality assessment was maintained for 4 of 4 instrument records reviewed. Findings include: 1. On the date of the Complaint Investigation Investigation(04/11/2018), Laboratory Maintenance Records revealed the Laboratory Director failed to review and sign the following maintenance logs: Horiba ABX Pentra XL March 2018 Sysmex CA 600 February 2018 and March 2018 Tosoh HPLC G8 January 2018, February 2018, and March 2018 Tosoh AIA-900 February and March 2018 2. The laboratory failed to report patient tests promptly. Refer to D5403. 3. The laboratory the laboratory failed to documment monthly maintenance for the Horiba Pentra XL analyzer. Refer to D5429 4. The Laboratory Director failed to ensure a sufficient number of laboratory personnel were available to accurately perform tests and report test results. Refer to D6028. 5. During the Complaint Investigation on (04/11/18), the Laboratory Testing Personnel confirmed the above findings.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:  
 By interview of the Laboratory Operations Manager, Laboratory Testing Personnel, and review of the test volume estimation records, at the time of the Complaint Investigation (14:30 04/11/2018), the Laboratory Director failed to ensure a sufficient number of laboratory personnel were available to accurately perform tests and report test results. Findings: 1. On the date of the Complaint Investigation, one Laboratory Testing Personnel was employed to perform laboratory testing. 2. The laboratory failed to have a procedure containing details specific to patient test reporting. Refer to D5403. 3. The laboratory the laboratory failed to document monthly maintenance for the Horiba Pentra XL analyzer. Refer to D5429. 4. The annual estimated test volume from the last CMS compliance survey (08/24/2017, was 153,094 non waived tests in 4 specialties. 5. On the date of the Complaint Investigation.the Laboratory Operations Manager confirmed the above findings.