

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0904344	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Northwest Physicians Associates Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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: Based on observation and interview with the Laboratory Working Manager at the time of the survey (10:30 05/09/2019), the laboratory failed to document maintenance for 2 of 2 microscopes. Findings include: 1. The Laboratory failed to document microscope maintenance after February 2017 for the (Hund Wetzlar) microscope, and the (Leica DM 750) microscope, used for reading urine sediments. 2. Observation of the Microscopes revealed, both microscopes had maintenance stickers dated (02/2017). 3. During the survey (10:30 05/09/2019), the Laboratory Working Manager confirmed the above findings.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:

Based on, the review of testing personnel competency assessment records, and testing personnel interview the Laboratory Director failed to ensure competency was maintained for 1 of 2 testing personnel, who performed patient testing on the Beckman Coulter AU 480 Chemistry Analyzer. from (04/12/2019), through date of survey (05/09/2019). Findings: 1) On the date of survey (05/09/2019), the laboratory's testing personnel competency assessment records, revealed Testing Personnel 1 did not have an annual competency assessment performed within 12 months of the previous competency performed (04/12/2018), for the Beckman Coulter AU 480 Chemistry Analyzer. 2) During the survey (13:00 05/09/2019), Testing Personnel 1 confirmed the above finding.