

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0011263	<b>(X3) Date Survey Completed</b>  04/07/2021
<b>Name of Provider or Supplier</b>  Penn Highlands Elk	<b>Street Address, City, State</b>  763 Johnsonburg Road, Saint Marys, 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>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's competency procedure and interview with general supervisor (GS) #3, the laboratory failed to follow their written procedure to assess 17 of 24 testing personnel (TP) for each individual test system they performed testing on in 2019 and 2020. Findings include: 1. The laboratory's competency procedure, point #3 states, "Competency assessment must include all six elements described below for each individual of each test system during each assessment period, unless an element is not applicable to the test". 2. On the day of survey, 04/06/2021, the laboratory was unable to provide competency assessment records for 17 of 24 TP, including all six elements for each test system a TP performed testing on in 2019 and 2020. 3. The GS #3 confirmed the findings above on 04/06/2021 around 3:45 pm.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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)</p>

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.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's procedure manual and interview with general supervisor (GS) #3, the laboratory failed to include control procedures in the post vasectomy, manual differential and body fluid microscopic examination procedures from 9/12/2018 to the day of survey. Findings include: 1. On the date of survey, 04/07/2021, review of the laboratory's procedure manual revealed, the post vasectomy, manual differential and body fluid microscopic examination procedures did not include and describe control procedures from 9/12/2018 to 04/07/2021. 2. The GS #3 confirmed the finding above on 04/07/2021 around 12:00 pm.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on observation of the urinalysis microscope and interview with the general supervisor (GS) #3, the laboratory failed to document maintenance for 1 of 1 Nikon E400 Eclipse microscope from January 2019 to April 6, 2021. Findings include: 1. Observation of the Nikon E400 Eclipse microscope's maintenance sticker stated, "Inspected 1/2018 - due 1/2019". 2. On the day of survey, 04/06/2021, The laboratory was unable to provide documentation of maintenance performed on 1 of 1 Nikon E400 Eclipse microscope used for manual microscopic urinalysis examinations from January 2019 to April 6, 2021. 3. The laboratory performed maintenance on the microscope on 04/06/2021. 4. The GS #3 confirmed the findings above on 04/06/2021 around 2:15 pm.