

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0011263	<b>(X3) Date Survey Completed</b>  07/30/2018
<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>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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> <p>This STANDARD is not met as evidenced by: Based on record review and interview of the Medical Laboratory Director (MLD) and the Laboratory Administrative Director (ALD) at the time of complaint investigation, Pennhighland Elk laboratory failed to ensure that the phlebotomist and radiology technician collecting patient specimens at the offsite collection facility were trained and competent before conducting blood draws at the Saint Marys Community Medical Building (SMCMB). Findings Include: 1. The Phlebotomist involved in the 03/21 /2018 patient misidentification incident at SMCMB is leased by Penn Highlands Elk. 2. All laboratory specimens collected at the SMCMB are sent to Penn Highlands Elk. 3. The laboratory could not provide any training or competency evaluation records performed by Penn Highlands Elk for 2 laboratory staff (phlebotomist and radiology technician) involved in the patient misidentification incident that occurred on 03/21 /2018 4. The MLD and ALD interviewed on 07/30/2018 at 3:00 PM confirmed that 2 of 2 laboratory staff involved in the patient misidentification incident were not trained by Penn Highlands Elk.</p>

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on observation, review of manuals and interview of the phlebotomist and radiology technician at the time of complaint investigation, the laboratory failed to ensure that an approved blood draw procedure was available to the Penn Highlands Elk staff at the off site collection facility (SMCMB). Findings Include: 1. At the time of complaint Investigation on July 30, 2018, the surveyors requested the Penn Highland Elk blood draw procedure from the phlebotomist who registered the complainant on 3/21/2018 and the radiology technician. They could not provide the Penn Highlands Elk Blood Draw Procedure. 2. The phlebotomist interviewed at 02:45 PM on 07/30/2018 confirmed that there was no Penn Highlands Elk Blood Draw Procedure manual onsite.