

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0181786	<b>(X3) Date Survey Completed</b>  10/08/2024
<b>Name of Provider or Supplier</b>  Penn Highlands - Brookville	<b>Street Address, City, State</b>  100 Hospital Rd, Brookville, 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>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, patient test reports and interview with the Technical Supervisor #2 (CMS 209 TS #2) the laboratory failed to examine 5 of 5 API PT hematology testing events in the same manner as patient specimens from 02/06/2023 to the date of survey. Findings include: 1. On the day of survey, 10/07/2024, review of the patient test reports and API PT records revealed that the laboratory failed to examine 5 of 5 API PT hematology testing events for semen analysis in the same manner as patient specimens from 02/06/2023 to 10/07/2024. 2. The laboratory's procedural manual titled "Post-Vasectomy Sperm Screen" stated the following: "7. Examine 100 field on the slide under high power, noting the presence and motility of any sperm present." "12. Report out results as: No sperm present per 100 HPF examined or XX-XX motile or nonmotile sperm present per 100 HPF examined." 3. Review of patient test reports revealed the laboratory reported the following quantitative semen analysis results: 02-23-080-0214 (03/21/1023): Sperm 0-2/HPF Sperm motility: Non Motile 02-23-219-0189 (08/07/2023): Sperm 2-4/HPF Sperm motility: Approximately 25% of sperm present had moderate motility. Remaining 75% were nonmotile. 4. API PT records showed the laboratory reported the following for semen analysis: - presence/absence</p>

(qualitative) of sperm. 5. TS #2 confirmed the finding above on 10/08/2024 at 01:00 pm.

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with Technical Supervisor #2 (CMS 209 TS #2) the laboratory failed to provide BD BACTEC blood culture temperature records in Microbiology from 02/06/2024 to the day of survey. Findings include: 1. On the days of survey, 10/07/2024 and 10/08/2024, the laboratory could not provide temperature records for 2 of 2 BD BACTEC blood culture drawers from 02/06/2024 to 10/08/2024. 2. TS#2 confirmed the findings above on 10/08/2024 around 01:00 pm

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with technical supervisor #2 (CMS 209 TS #2), the laboratory failed to label aliquoted reagents with the pertinent information required for proper use in Microbiology from 02/06/2023 to 10/08/2024. Findings include: 1. On day of the survey 10/08/2024 at 12:30 pm, during the laboratory tour, observation of the Gram Stain reagents revealed 1 of 1 container used to aliquot BD Decolorizer was not properly labeled with the following: - identity of reagent - storage requirements - preparation and expiration dates 2. TS #2 confirmed the findings above on 10/08/2024 around 12:30 pm.