Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0011263	05/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Penn Highlands Elk	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with the Laboratory Administrative Director (LAD), the laboratory failed to verify at least twice annually the accuracy of Microbiology/Bacteriology testing performed for 2 of 2 years from 04/18/2023 to 05/07/2025. Findings include: 1. On the day of survey, 05/06/2025 at 12:37 pm, review of the laboratory's API PT records revealed the laboratory failed to verify the accuracy at least twice annually of the following examinations performed for Microbiology/Bacteriology in 2023 and 2024 for which compatible PT samples were not offered by API: 2023 and 2024: - Blood culture - CSF culture - Ear/Eye culture - Throat culture 2024: - Gram stain morphology - N. gonorrhoeae culture GCB 2. The laboratory reported an estimated annual volume of 24,440 for microbiology (CMS 116). 3. The LAD confirmed the above findings on 05/07/2025 at 10:58 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal

	values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, verification of performance specifications records, lack of documentation, and interview with the Laboratory Administrative Director (LAD), the laboratory failed to provide complete validation records for the required performance specifications for Chemistry and Hematology testing performed on 1 of 1 iSed Elite(SN 5732) erythrocyte sedimentation rate(ESR) analyzer and 2 of 2 Rapidpoint 500e(SN 55349 and 55442) blood gas analyzers before reporting patient results. Findings Include: 1. On the day of survey, 5/6/2025 at 10:30 am, the laboratory could not provide documentation of a reference range/normal value study appropriate for the laboratory's patient population for the following analyzers used for ESR examinations and Blood gas analyses. 1 of 1 iSed Elite SN 5732 2 of 2 Rapidpoint 500e SN 55349 and 55442 2. The LAD confirmed the above findings on 5 /7/2025 at 8:30 am.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the Laboratory Administrative Director (LAD), the Laboratory Director (LD) failed to ensure an approved corrective action plan was followed when the laboratory had unsatisfactory analyte performance for 2 of 6 API PT Microbiology/Bacteriology testing events in 2023 and 2024. Findings include: 1. On the day of survey, 05/06/2025 at 12:37 pm, review of the laboratory's API PT records revealed the laboratory scored below 80 percent for the following 2 of 6 API PT testing events in 2023 and 2024 for Microbiology/Bacteriology: - API 2023 Microbiology/Bacteriology 3rd event: Wound culture - Anaerobic 0% - API 2024 Microbiology/Bacteriology 1st event: Wound culture - Anaerobic 50% 2. The corrective action for the unsatisfactory analyte performance due to tech error was to perform education. 3. The LAD confirmed the findings above on 05/07/2025 at 10:58 am.