Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0011263	04/20/2023
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's procedures, competency assessment records and interview with technical supervisor (TS) #2, the laboratory failed to follow their competency assesment procedure to assess the competency of 7 of 8 Technical supervisors (TS), 4 of 10 technical Consultants (TC) and 1 of 4 general supervisors (GS) for their supervisory responsibilities in 2021 . Findings include: 1. The laboratory's competency assesment procedure states: " The supervisor competency record will be completed annually by the laboratory director for each employee acting as a TC, TS, or GS. 2. On the day of the survey, 04/18/2023 at 8:30 am, the laboratory could not provide documentation for the competency assessment of the following in 2021: - 7 of 8 TS (CMS 209 personnel #2, #3, #4, #5, #6 , #9, and #16). - 4 of 10 TC (CMS 209 personnel #7, #8, #10, and #12) - 1 of 4 GS (CMS 209 Personnel #15) 3. The TS#2 confirmed the findings above on 04/20/2023 around 12:00 pm B. Based on review of the laboratory's procedures, competency assesment records and interview with the technical supervisor (TS) #2, the laboratory failed to follow their competency assesment procedure to assess the competency of 18 of 18 testing personnel (TP) who performed potassium hydroxide (KOH) and wet mounts microscopic examinations from 04/07/2021 to the date of survey. Finding Include: 1. The laboratory's competency assesment procedure states:"Element of competency includes: - "Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; - Monitoring the recording and reporting of test results; -Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; -

	Direct observations of performance of instrument maintenance and function checks; - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and - Assessment of problem solving skills." 2. On the day of survey 04/19/2023 at 09:20 am, Review of competency assessment reports for (KOH) and Wet mounts microscopic examinations were missing the following 5 of 6 procedures in the assessment for 18 of 18 TP: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; - Monitoring the recording and reporting of test results; - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; - Direct observations of performance of instrument maintenance and function checks; - Assessment of problem solving skills 3. The TS#2 confirmed the finding above on 04/20/2023 around 12:00 pm
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Technical Supervisor (TS)#2, the laboratory failed to evaluate the accuracy of the non graded results obtained for 2 of 3 API events in 2021 and 1 of 3 API events in 2022 in Microbiology. Findings Include: 1. On the day of survey, 04/19/2023 at 09:45 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analytes in microbiology that were not graded by the PT agency: - API 2021 (2nd Event): Blood Culture MIC/zone Diameter and interpretation of susceptibilities, Urine Culture MIC /zone diameter - API 2021 (3rd Event): Urine Culture MIC/zone diameter - API 2022 (1st Event): Gram stain (GS-05). 2. The laboratory's annual volume for microbiology is 15285 (CMS116) 3. TS#2 confirmed the findings above on 04/20/2023 around 12: 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 the laboratory observations, review of temperature records and interview with Technical Supervisor (TS) #2, the laboratory failed to document daily room temperatures in hematology where instruments and supplies were stored from 04/07 /2021 to the day of survey. Findings Include: 1. On the day of survey , 04/20/2023 at

	10:50 am., During the laboratory tour it was observed that the temperature in Hematology was colder than the temperature in the coagulation department. The thermometer to record room temperatures was located in the coagulation department 2. Record review revealed that the room temperature for hematology and coagulation were taken only in the the coagulation department. 3. The laboratory could not provide separate room temperature records for the hematology department. 4. The TS #2 confirmed the findings above on 04/20/2023 around 12:00 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 validation records, review of the laboratory's validations procedures and interview with the Technical Supervisor (TS)#2, the laboratory failed to establish criteria for acceptable performance specifications for 1 of 1 analytes on the Siemens Vista 500 chemistry analyzers, 3 of 3 analytes on the Siemens Centaur analyzers, 2 of 2 Siemens Rapid Point 500 blood gas analyzers, 2 of 2 Sysmex XN10 hematology analyzers, and 1 of 1 analytes in microbiology in 2021 and 2022. Findings Include: 1. On the days of the survey, 04/18/2023, 04/19/2023 and 04/20/2023, review of the validation records revealed the following validations did not include criteria for acceptable precision, accuracy and reportable ranges: - 1 of 1 analytes on the Siemens Vista 500 chemistry (high sensitivity troponin) validation done in 2021 - 3 of 3 analytes on the Siemens Centaur analyzers (Estradiol, Luteinizing hormone (LH), Follicle-stimulating hormone (FSH)) Validation done in 2021 - 2 of 2 Sysmex XN10 hematology analyzers validations done in 2022 2. The laboratory could not provide the acceptance criteria for the 1 of 1 qualitative microbiology analytes (campylobacter antigen) validation done in 2022. 3. The laboratory could not provide acceptance criteria for when they relocated 2 of 2 Siemens Rapid Point 500 blood gas analyzers in 2022. 4. The laboratory could not provide a complete procedure for validations of new instruments, analytes, methodology and relocation of instruments. 5. The TS#2 confirmed the findings above on 04/20/2023 around 12:00 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) and interview with the Technical Supervisor (TS)#2, the laboratory failed to include 1 of 3 parts for IQCP's established in Microbiology, hematology, and immunology when implementing an individualized quality control plan from 04/07/2021 to the days of survey. Findings include: 1. On the days of the survey, 04/18/2023, 04/19/2023 and 04 /20/2023, review of the laboratory's individualized quality control plans revealed that the laboratory failed to include a Quality Control Plan (QCP) which is 1 of 3 parts of an IQCP for the following tests: - Leuko EZ vue - Shiga toxin - Qiastat- dx - Mononucleosis. - Campyplobacter Antigen. 2. Record review revealed that the quality control plan referred to manufacturer's' instructions which state to follow federal, state and local regulations. 3. The TS#2 confirmed the findings above on 04/20/2023 around 12:00 p.m.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of comparison studies records and interview with the Technical Supervisor (TS)#2, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments in hematology, chemistry, and coagulation from 04/07/2021 to the date of the survey. Findings include: 1. On the days of the survey, 04/18/2023, 04/19/2023 and 04/20/2023, the laboratory failed to provide documentation of the biannual comparison studies for the following instrumentation: 2021: - One comparison study for 2 of 2 Siemens Vista 500 #1 analyzers in chemistry. - Two comparison studies for 2 of 2 Rapid Point 500 blood gas analyzers - Two comparison studies for 2 of 2 ACL top 350 analyzers in coagulation - One comparison study between automated differential and manual differential in hematology 2022: - One comparison study for 2 of 2 ACL top 350 analyzers in coagulation - Two comparison studies between automated differential and manual differential in hematology 2. Results of comparison studies were not reviewed and signed by the laboratory director or designee for the following instrumentation: - 2 of 2 Siemens Vista 500 in October 2021, June 2022 and December 2022. - 2 of 2 Rapid Point 500 #1 in May 2022 and October 2022. 3. TS#2 confirmed the findings above on 04/20/2023 around 12:00 pm.