Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0184808	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Penn Highlands Tyrone	187 Hospital Drive, Tyrone, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of documentation and an interview with General Supervisor (GS) #1, the laboratory failed to verify twice annually the accuracy of nicotine examinations performed from 11/11/21 through the date of the survey. Findings include: 1. On the day of the survey, 12/07/2022 at 12:09 pm, the laboratory could not provide documentation of verification of accuracy for nicotine examinations performed from 11/11/2021 to 12/08/2022. 2. GS #1 confirmed the findings above on 12/08/2022 around 03:00 pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with General Supervisor (GS) #1, the laboratory failed to document the evaluation and verification activities for PT testing performed in microbiology, chemistry, hematology/coagulation, and immunology /immunohematology from 09/17/2020 to the date of the survey. Findings Include: 1. On the day of the survey, 12/07/2022 at 08:25 am, a review of API proficiency testing records revealed that the laboratory did not document the review and corrective action taken for the following PT events that received an unacceptable grade from 09/17

	/2020 to 12/08/2022: -80% on API 2022 1st event Chemistry Core: Gentamicin and B-type natriuretic peptide (BNP) -50% on API 2020 3rd event Microbiology: Microscopy Potassium Hydroxide (KOH) Preparation -80% on API 2021 2nd event Chemistry Core: Salicylate and partial pressure of carbon dioxide (pCO2). 2. The laboratory could not provide documentation of the verification of accuracy for the following PT events that were not graded by the PT testing agency: -2022 Microbiology 3rd Event: Urine Culture MIC/Zone Diameter Value -2020 Hematology /Coagulation 3rd Event: Blood Cell Identification, Fibrinogen, Urine Sediment, Reticulocyte. -2020 Immunology/Immunohematology 3rd Event: Antibody Screen, Direct Antiglobulin Test-Polyspecific. -2020 Microbiology 3rd Event: Wound Culture, Urine Culture MIC/Zone Diameter Value -2021 Hematology/Coagulation 1st Event: Fibrinogen, Reticulocyte. -2021 Hematology/Coagulation 3rd Event: Urine Sediment. -2021 Immunology/Immunohematology 3rd Event: Direct Anitglobulin Test-Polyspecific. -2021 Microbiology 1st Event: CSF Culture MIC/Zone Diameter, Cerebral Spinal Fluid (CSF) Culture Susceptibility, Urine Culture MIC/Zone Diameter Value, Urine Culture Susceptibility. -2021 Microbiology 2nd Event: Blood Culture MIC/Zone Diameter, Blood Culture Susceptibility, Urine Culture MIC/Zone Diameter Value. -2021 Microbiology 3rd Event: Urine Culture MIC/Zone Diameter Value. -2022 Microbiology 1st Event: CSF Culture MIC/Zone Diameter, CSF Culture Susceptibility, Urine Culture MIC/Zone Diameter Value, Gram Stain. -2022 Immunology/Immunohematology 1st Event: Compatibility. -2022 Immunology /Immunohematology 1st Event: Compatibility. 3. The laboratory could not provide documentation that the following API PT attestation sheets were reviewed and assessed by the LD or designee: -2021 Chemistry Core 1st Event -2021 Chemistry Core 2nd Event -2021 Chemistry Core 3rd Event -2021 Hematology/Coagulation 3rd Event -2021 Microbiology 1st Event -2021 Microbiology 2nd Event -2021 Chemistry Miscellaneous 2nd Event 4. GS #1 confirmed the findings above on 12/08/2022 at 03: 00 PM.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the lack of documentation, review of laboratory records, and interview with General Supervisor (GS) #1, the laboratory director failed to provide overall management and direction in accordance with 42 CFR 493.1445. Refer to D6093, D6094, D6095, and D6103. Findings include: 1. Failure to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6093. 2. Failure to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094. 3. Failure to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system (calibration verification/comparison studies). Refer to D6095. 4. Failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing to assure they are competent. Refer to D6103.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and an interview with General Supervisors (GS) #1 and #2 , the laboratory director (LD) failed to ensure that a QC program was established and maintained to ensure the quality of services provided for testing performed in chemistry, hematology, and microbiology from 09/17/2020 to the date of the survey. Findings Include: 1. On the day of the survey, 12/07/2022 at 04:00 pm, review of laboratory records revealed that the laboratory did not follow the Individualized Quality Control Plan (IQCP) implemented that states QC will be performed weekly for microbiology testing performed on the Siemens Autoscan. 2. The laboratory could not provide documentation of the weekly QC performed on the Siemens Autoscan for 11 of 37 weeks from 01/01/2022 to 09/08/2022. 3. On the day of the survey, 12/08/2022 at 12:00 pm , the laboratory could not provide documentation for the following: - Quality control for manual cell counts performed using a hemacytometer from 09/17/2020 to 12/08/2022. - Corrective actions taken when results of hematology and chemistry controls failed to meet the laboratory's established criteria for acceptability. - Daily quality control for 9 of 31 days in January 2021 for the Abbott Cell-Dyn Ruby hematology analyzer. - Daily background checks for 19 of 31 days in January 2021 for the Abbott Cel-Dyn Ruby hematology analyzer. 7. GS # 1 confirmed the findings above on 12/09/2022 at 03:00 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a lack of documentation, a review of the laboratory procedure manual, and an interview with General Supervisor (GS)#1, the Laboratory Director (LD) failed to ensure quality assessment (QA) programs were established and maintained to assure the quality of laboratory services provided from 09/17/2020 to the day of the survey. Findings Include: 1. On the date of the survey, 12/07/2022 at 11:56 am, the laboratory could not provide a QA procedure or documentation of periodic evaluation of the laboratory that assessed the laboratory's pre-analytical, analytical, and post-analytical processes from 09/17/2020 to 12/07/2022. 2. GS #1 confirmed the findings above on 12/08/2022 around 03:00 pm.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

	This STANDARD is not met as evidenced by: A. Based on the lack of documentation and interviews with General Supervisors (GS) #1 and #2 , the Laboratory Director (LD) failed to ensure that the laboratory evaluated twice a year the relationship between test results for 2 of 2 Abbott Cell-Dyn hematology analyzers, 2 of 2 Siemens Dimension EXL chemistry analyzers, and differential blood counts (automated and manual) from 09/17/2020 to the date of the survey. Findings include: 1. On the day of the survey, 12/08/2022 at 10:43 am, the laboratory could not provide comparison of test results between the following instruments or methodologies from 09/17/2020 to 12/08/2022: - 2 of 2 Siemens Dimension EXL analyzers (routine chemistry, endocrinology, toxicology) - 2 of 2 Abbott Cell-Dyn Emerald and Ruby analyzers (complete blood count with differential) - Differential blood counts (automated and manual counts) 2. GS #1 confirmed the findings above on 12/08/2022 at 03:00 pm. B. Based on the lack of documentation and interview with General Supervisor (GS) #1 , the laboratory failed to perform calibration verification at least once every six months for the Siemens Dimension Chemistry EXL Analyzer from 09/17/2020 to the date of the survey. Findings include: 1. On the date of the survey, 12/08/2022 at 01:00 pm, the laboratory could not provide calibration verification records for the required analytes tested on the Siemens Dimension EXL chemistry analyzer from 09/17/2020 to 12/08/2022. 2. GS #1 confirmed the findings above on 12/08/2022 around 03:00 pm.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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. This STANDARD is not met as evidenced by: Based on a review of personnel competency assessment records and an interview with General Supervisor (GS) #1 , the Laboratory Director (LD) failed to assure the competency of 8 of 8 testing personnel (TP) performing examinations in chemistry, hematology, immunology, and microbiology were assessed and documented from 2020 to the date of the survey. Findings Include: 1. On the day of the survey, 12/07 /2022 at 09:47 am, the laboratory could not provide documentation of competency assessment performed on 8 of 8 TP for the following examinations performed in chemistry, hematology, immunnology, and microbiology from 2020 to the date of the survey: - Manual Body Fluid (Hemacytometer) - Wet Mount (Yeast, Trichomonas, Bacterial Vaginosis) - Rheumatoid Factor (Biokit Rheumajet RF) - Mononucleosis (SureVue Color Mono) - Rapid Human Immunodeficiency Virus (Alere HIV-1/2 Combo) - Sedimentation Rate (Sediplast Westergren ESR System) - Nicotine (Nicotine Status DM) 2. GS #1 confirmed the findings above on 12/08/2022 around 03:00 pm.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification

	requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the General Supervisor (GS)#1, the laboratory failed to ensure that each individual who performed High Complexity testing (1 of 8) met the CLIA requirement 493.1489b. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the

	factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a review of the CLIA's Laboratory Personnel Report (Form CMS-209), a review of personnel qualification records, and an interview with General Supervisor (GS) #1, the laboratory failed to ensure that each individual performing high complexity testing (1 of 8 TP) had the minimum qualifications required from 06/06/2022 to the day of the survey. Findings Include: 1. On the date of the survey, 12/07/2021 at 09:23 am, review of the testing personnel qualification records revealed that 1 of 8 testing personnel (CMS 209 personnel # 6) who performed high complexity testing in immunohematology, hematology, and microbiology from 06/06/2022 through 12/08/2022, did not have the minimum qualifications. 2. GS # 1 confirmed the findings above on 12/08/2022 at 03:00 pm.