Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0181786	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Penn Highlands - Brookville	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A. Based on the American Proficiency Institute (API) proficiency testing (PT) records and interview with the General Supervisor (GS) #1, the Laboratory Director (LD) failed to sign the API PT attestation statement from 2018, 2019, and 2020. Findings include: 1. On the day of survey, 11/03/2020, review of API PT records revealed, the following API PT attestation statements were not signed by the LD: - 2018, Event #3, Hematology/Coagulation. - 2019, Event #1, Chemistry Core (Blood Gases). - 2020, Event #1, Immunohematology. 2. The GS confirmed the findings above on 11/04 /2020 at 12:30 p.m. B. Based on American Proficiency Institute (API) proficiency testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to provide attestation statements from 2018, 2019, and 2020. Findings include: 1. On the day of survey, 11/04/2020 review of API PT records revealed the following API PT attestations statements were missing: - 2018 Event #3, Chemistry Core (Blood gases). - 2019 Event #1 Hematology/Coagulation. - 2019 Event #2 and Event#3, Chemistry Core (Blood gases). - 2020 Event #1 and Event #2, Chemistry Core (Blood gases). 2. The GS confirmed the findings above on 11/04/2020 at 12:30 p.m.

D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on observation of the Blood Bank refrigerator and interview with General Supervisor (GS) #1,the laboratory failed to ensure areas were designated in the blood bank refrigerator for quarantine blood products from 09/19/2018 to the date of survey. findings include: 1. On the day of survey, 11/03/2020, observation of the blood bank refrigerator revealed, there were no designated areas for quarantine blood products in the blood bank refrigerator. 2. The GS#1 confirmed the finding above on 11/03/2020 at 11:35 a.m. 3. The GS#1 corrected the deficiency on-site on 11/04/2020.
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: Based on review of the laboratory's Continue Education and Competency Assessment Policy, and interview with the General Supervisor (GS) #1, the laboratory failed to establish a complete procedure for the assessment of 2 of 2 General Supervisors for their supervisory responsibilities, 7 of 7 Testing Personnel (TP) for each test performed in Microbiology, Immunology, Chemistry, Hematology, and Immunohematology departments, and 9 of 9 of testing personnel who performed blood gases were not assessed for competencies from 09/19/2018 to the day of survey. Findings include: 1. On the day of survey, 11/03/2020, the GS#1 could not provide a General Supervisor policy to assess the competency of 2 of 2 GS for their supervisory responsibilities in 2018,2019, and 2020. 2. Review of the personal records revealed 9 of 9 TP who performed blood gases testing, were not assessed for competency in 2018, 2019, and 2020. 3. Review of the competency assessment record revealed, the laboratory did not assess 7 of 7 TP for each individual tests performed in the in Microbiology, Immunology, Chemistry, Hematology, and Immunohematology departments in 2018, 2019 and 2020. 4. The GS #1 confirmed the finding above on 11 /04/2020 around 12:30 p.m.
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 review of temperature records and interview with General Supervisor (GS) #1, the laboratory failed to record daily temperatures on the Medication Refrigerator and room temperature where the blood gases supplies were store from 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 11/04/2020, review of the Medication Refrigerator records revealed, the following number of days temperatures were not documented each month: 2018: - 4 of 30 days in September. - 2 of 31 days in October. - 2 of 31 days in December. 2019: - 6 of 31 days in January. - 2 of 28 days in February. - 3 of 31 days in March. - 5 of 30 days in April. - 5 of 30 days in June. - 4 of 31 days in July. - 4 of 31 days in August. - 2 of 30 days in September. - 2 of 31 days in October. - 3 of 30 days in November. -7 of 31 days in December. 2020: -7 of 31 days in January. - 6 of 29 days in February. - 4 of 31 days in March. 2. Review of temperature records revealed, room temperatures were not taken where blood gases reagents were store from 2018, 2019, and 2020. 3. The GS #1 confirmed the finding above on 11/04/2020 around 12:30 p.m.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based upon a review of the Chemistry Instrument Calibration-AMR-Precision policy, review of Siemens Dimension Vista 500 calibration verification records, and interview with Testing Personnel (TP) #4 the laboratory failed to follow perform semiannual calibration verification from 01/01/2020 through 10/24/2020 . Findings include: 1. The Chemistry Instrument Calibration-AMR-Precision policy states: "Calibration verification is performed at a minimum of every six months for all Vista methods". 2. On the day of survey, 11/04/2020, review of the Siemens Dimension Vista 500 (SN DV330217 and DV370126) records revealed, one calibration verification was perform during 2020 (October 24) for the following 35 analytes: -

	Blood urea nitrogen - Calcium - Cholesterol - Creatinine 2 - Glucose - Lactate - Magnesium - Uric Acid - Phosphorus - Salicylate - Triglycerides - Ammonia - Carbon Dioxide - Ethyl Alcohol - Albumin - Total Protein - Alkaline Phosphatase - Acetaminophen - Direct Bilirubin - Total Bilirubin - High-density lipoproteins - Low-density lipoproteins - Total Iron Binding Capacity - Iron - Amylase - Gamma Glutamyltransferase - Lipase - Alanine Aminotransferase - Aspartate Aminotransferase - Lactate Dehydrogenase - Creatine Kinase - Sodium - Potassium - Chloride - Urinary/Cerebrospinal Fluid Protein (UCFP). 3. TP #4 confirmed the finding above on 11/04/2020 around 09:30 a.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Quality Control (QC) records and interview with General Supervisor (GS) #1, the laboratory failed to establish and document QC procedures for Post Vasectomy Microscopic Examinations and for immuno group and RH typing by tube method from 2018, 2019, 2020. Finding include: 1. On the day of survey, 11/03/2020, review QC records revealed the laboratory did not document QC for Post Vasectomy Microscopic examinations and immuno group and RH typing by tube method from 09 /19/2018 to the date of survey. 2. The GS #1 confirmed the finding above on 11/04 /2020 around 12:30 p.m.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) records and interview with the General Supervisor (GS) #1, the laboratory failed to check each batch or shipment of blood culture bottles media for its ability to support growth from 2018, 2019 and 2020. Findings include: 1. On the day of survey, 11/03/2020, review of blood culture media QC records revealed, the laboratory did not check each batch or shipment of blood culture media bottles for its ability to support growth from 2018, 2019 and 2020. 2. The GS #1 confirmed the finding above on 11/04/2020 around 12:30 p.m.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)

	The laboratory director must ensure 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 American Proficiency Institute (API) reports and interview with General Supervisor (GS) #1, the Laboratory Director (LD) failed to ensure that an approved corrective actions were documented for unacceptable PT results in 2019. Findings include: 1. On the day of survey, 11/04/2020, review of the API PT records revealed the following PT reports did not have an approved corrective action documented: - 2019 Event#2 Chemistry-Core (Blood Gases) 80%. - 2019 Event #3 Chemistry-Core (Blood Gases) 80%. 2. The Laboratory director did not signed the following PT corrective actions: - 2019 Event#2 Chemistry-Core (Blood Gases). - 2019 Event #3 Chemistry-Core (Blood Gases). - 2020 Event #3 Chemistry-Core (Blood Gases). 3. The GS #1 confirmed the finding above on 11/04/2020 around 12: 30 p.m.