

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0181725	(X3) Date Survey Completed 07/29/2022
Name of Provider or Supplier Penn Highlands Dubois	Street Address, City, State 100 Hospital Avenue, Du Bois, 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
D0000	A focused unannounced complaint survey was held on July 28, 2022 and July 29, 2022 based on repeated proficiency testing failures for blood gas analytes.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Refer to D2006, D2011, and D2015.</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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>

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interviews the laboratory failed to rotate testing personnel, with 2 of 27 testing personnel performing PT (proficiency testing) in the past 3 of 6 regulatory PT cycles and 2 of 2 PT off-cycle events for blood gas analytes. Findings: 1. The laboratory's policy "Proficiency Testing," states: "Proficiency testing samples are rotated among the staff who perform patient testing." 2. Based on a review of the "Penn Highlands DuBois pO2 Proficiency Testing and Solution Pack Details" document TP#1 performed two regulatory testing events: API 2021 2nd Event, CAP 2022 1st event, and two off-cycle events: CAP 2021 2ND event and CAP 2021 3rd event. TP#2 performed API 2021 3rd event. 3. Twenty-seven personnel are trained to perform testing on blood gas analytes, based on the indication of personnel on the CMS 209 by TP#2.

D2011

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Based on interview and record review, the laboratory failed to ensure that inter-laboratory communications did not take place pertaining to the results of proficiency testing samples. Findings: 1. During the survey on 7/28/2022, TP#2 explained that testing personnel commonly rotated between separate CLIA sites falling under the same hospital system. When asked how the laboratory ensures that the same PT events are not run by the same testing personnel at separate sites TP#2 explained that he has run the previous PT event at two CLIA separate sites. 2. During record review, College of American Pathologist Event 2 2022 SO-B and AQ-B had been both documented as run by the same testing personnel at Penn Highlands Du Bois and Penn Highlands Clearfield (CLIA 39D0185151).

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:
 Based on a lack of documentation and interview, the laboratory failed to maintain attestation statements and analyzer printouts for 3 of 6 regulatory PT events reviewed. Findings: 1. The laboratory's policy titled "Proficiency Testing" states: " All records of proficiency testing are maintained for at least two years from the date of participation. The following records are kept: each proficiency testing result, test handling, preparation, processing, examination, each step in the testing, signed attestation statement(s) provided by the proficiency program, a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results, corrective action taken". 2. During the survey on July 28, 2022, the laboratory failed to provide raw data for proficiency testing for API event 2 of 2021 for blood gas analytes including pO2 and methemoglobin. The records had been requested by the surveyor on July 28, 2022, at about 9:30 am and were not provided to the surveyors prior to the conclusion of the survey on July 29, 2022, at approximately 11:00 am. 3. The surveyor requested the records of the PT attestation for CAP SO-A 2022, and CAP SO-B 2022 at 9 am on July 29, 2022 and the laboratory was unable to provide the records to the surveyor prior to the end of the survey at 11:00 am on July 29, 2022. 4. During an interview on July 29, 2022, at approximately 10:00 am TS#1 stated the laboratory was unable to obtain the requested PT attestations.

D2016

SUCCESSFUL PARTICIPATION
 CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:
 Based on record review and interview, the laboratory failed to successfully perform proficiency testing for the analytes pO2 and methemoglobin, by achieving 80% during 3 of the past 6 proficiency testing events for each analyte. Refer to D2087.

D2087

ROUTINE CHEMISTRY
 CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to successfully perform proficiency testing for the analytes pO2 and methemoglobin, by achieving 80%, during 3 of the past 6 proficiency testing events for each analyte. 1. A review of the laboratory's proficiency testing records from the College of American Pathologist (CAP) proficiency testing program showed the following scores for methemoglobin: Event 1 2021: 40% Event 2 2021: 40% Event 3 2021: 40% 2. A record review of the CASPER 0155D report and the laboratory's proficiency testing records from the College of American Pathologist (CAP) proficiency testing program showed the following scores for PO2: Event 1 2021: 40% Event 3 2021: 60% Event 1 2022: 40% 3. In an interview on July 28, 2022 at approximately 5:30 PM the laboratory director confirmed the above findings.

D3031

RETENTION REQUIREMENTS
 CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to retain the printouts for 5 of 5 analyzers' Radiometer ABL90FLEX PLUS analyte performance verification (calibration verification), method comparison, quality control, and maintenance records related to blood gas testing in the laboratory. Findings Included: 1. Review of the analyte performance verification (calibration verification) sheet showed that they were performed on 5 analyzers' in March 2020, August 2020, February 2021, August 2021, March 2022, and April 2022. 2. Review of the method comparison sheet showed that they were performed on 5 analyzers in September 2020, February 2021, August 2021, and April 2022. 3. The surveyor requested printouts for the analyzers for the analyte performance verification (calibration verification) and method comparison on July 28, 2022 at 4:00 PM. The laboratory failed to provide the printouts prior to the end of the survey on July 29, 2022 at 11:00 am. 4. The surveyor requested 2021 and 2022 Quality Control records for the laboratory's five Radiometer Blood Gas analyzers on July 28, 2022 at approximately 2:30 PM. The laboratory was unable to provide the records prior to the end of the survey on July 29, 2022 at 11:00 am. 5. The surveyor requested 2021 and 2022 Maintenance records for the laboratory's five Radiometer Blood Gas analyzers on July 28, 2022 at approximately 2:30 PM. The laboratory was unable to provide the records prior to the end of the survey on July 29, 2022 at 11:00 am. 6. In an interview with TP#2 on 7/28/2022 at 4 PM, he was not able to provide printouts for 5 analyzers for the analyte performance verification (calibration verification) and method comparison.

D5403

PROCEDURE MANUAL
 CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
 Based on record review the laboratory failed to ensure procedures for blood gas testing met regulatory requirements. Findings: 1. The laboratory's procedures "Blood Gas Rapid Point 500 General Procedure" and "Sample Analysis-RapidPoint 500e" does not contain the preparation of materials used for testing, calibration and calibration verification procedures - including what to do if calibration fails, control procedures - including the levels of control, control limits, criteria to determine acceptable control results, limitations in the test methodology, reference intervals, critical values, and a description of the course of action to take if a test system becomes inoperable.

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 document review and interview, the laboratory director failed to fulfill laboratory director responsibilities. Refer to D6079, D6082, D6089 and D6094.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

	<p>Based on a record review of the laboratory personnel competency assessment records and interviews, the laboratory failed to assess the competency of all testing personnel (TP) for competency in 2020 and 2021. Findings Included: 1. The personnel form CMS-209 filled out by the laboratory at the time of the survey listed 27 TP testing personnel for the respiratory therapy laboratory, (the laboratory had not delegated duties for a technical consultant in Chemistry on the CMS-209). 2. The surveyor requested the laboratory personnel competency assessment records in 2020 and 2021. The lab only provided 2 of 27 the competency of testing personnel in 2020 and 2021. 3. The laboratory failed to provide the competency of the remaining 25 of 27 testing personnel for 2020 and 2021 prior to the end of the survey on July 29, 2022 at 11:00 am. 4. In an interview with TP#2, on July 28, 2022 at approximately 3:40 PM, he confirmed the laboratory was not able to provide the missing competency of testing personnel in 2020 and 2021.</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure the Radiometer testing system used for Blood Gas testing in the laboratory from 2019-2022 provided quality laboratory services. Refer to D6094.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interviews the laboratory failed to rotate testing personnel, with 2 of 27 testing personnel performing PT (proficiency testing) in the past 4 of 6 regulatory PT cycles and 2 of 2 PT off-cycle events for blood gas analytes. Findings: Refer to D2006.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview the laboratory failed to establish and maintain sufficient quality assessment programs to identify failures in quality as they occur by failing to resolve proficiency testing failures in the laboratory. Findings: 1. The</p>

laboratory's "Laboratory Quality Assurance Plan" states: "External assessment of the Laboratory performance happens through accreditation, proficiency testing (PT), and performance of shared specimens for alternative PT or participation in inter-Laboratory QC programs" and "Proficiency testing provides accuracy information, comparison for validations, and troubleshooting material." 2. During a survey on July 28, 2022, the laboratory's proficiency testing records from the College of American Pathologist (CAP) proficiency testing program showed the following scores for methemoglobin: Event 1 2021: 40% Event 2 2021: 40% Event 3 2021: 40% 3. A record review of the CASPER 0155D report and the laboratory's proficiency testing records from the College of American Pathologist (CAP) proficiency testing program showed the following scores for PO2: Event 1 2021: 40% Event 3 2021: 60% Event 1 2022: 40% 4. The laboratory provided a document titled: "Corrective Action Checklist," for 2021 1st event. The document indicates it is for the following analytes: "pO2, HgB, and MethHb." The document's findings section states: "Machine appeared to be in order.. Possible user error." For Corrective Action, the document states: "Will continue to monitor for trends in ABG parameters. Calibration Verification occurred since the survey and prior to results. All values within range." The document was signed by TP#1 and TS#1 on 2/25/2021 and the LD on 3/15/2021. 5. The laboratory provided a document titled: "Corrective Action Checklist," for 2021 2nd event. The document is for methemoglobin. The document's findings section states: "Met Hb out." The form says: "Could patient results have been affected? If so, explain course of action" the laboratory wrote: "Continue to monitor." The Corrective Action taken portion of the form says: " continue to show issues w methb successful otherwise one parameter out for PO2 but remains satisfactory. All QC and calibrations are in." The form is signed by TP#1 on 6/26/2021 and the LD on 6/20/2021. 6. The laboratory provided a document titled: "Corrective Action Checklist," for 2021 3rd event. The document is for PO2 only, Methemoglobin is not addressed. The document's findings section states: "QC and Calibrations are satisfactory on this date as well as calibrations. QC being analyzed at 25 degrees PT (proficiency testing [sic]) being ran as pt (patient [sic]) samples at 37 degrees. These elevated temperatures cause elevates PO2 values." The Corrective Action portion of the form says: "Continue to monitor and request switch to CAP to see if we continue to have stated issues." The form is signed by TP#1 on 9/22/2021 and the LD on 9/22/2021. 7. During an interview on July 28, 2022 when asked if the laboratory investigated if other proficiency samples were tested at the wrong temperature per the proficiency testing instructions the LD said she did not know. 8. The laboratory provided a document titled, "Corrective Action Checklist." The document is for Event 1 2022. The document is for PO2. Under the Quality Control portion of the document, it says, "waiting for Radiometer to complete investigation and provide data." Under corrective action the form says: "Refer to pO2 Timeline of Investigation." The timeline indicates the root cause of the problem was that the proficiency testing was performed at the wrong temperature, the laboratory performed 7 off cycle samples of which 6 were successful, and the laboratory received the proficiency testing results on April 6, 2022. On April 6, 2022 the laboratory took the Radiometer analyzer (SN 092R0217N0038) which PT was performed on out of service per the corrective action timeline. The document "Corrective Action Checklist," is signed by the laboratory director on April 18, 2022. 9. Based on the document titled: "PO2 Timeline of Investigation" the laboratory removed a second Radiometer (SN 092R0281N0034) from service on April 13, 2022. On April 20, 2022 the laboratory removed the remaining 3 Radiometer analyzers from service. In an interview on July 28, 2022 around 5:40 PM the LD confirmed that she was on board with the decision to remove the analyzers from service and that the facility believe the laboratory was producing accurate results on their analyzers, though they had not rerun proficiency testing samples on either SN 092R0281N0034

or 092R0217N0038. 10. During an interview on July 28, 2022, TS#1 indicated that there was no standing meeting to discuss laboratory quality measures, only a hospital-wide quality meeting, and the following measures are discussed in that meeting: turnaround times, critical values, blood culture contamination rates, and pathology concordance.