

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0181725	(X3) Date Survey Completed 11/16/2023
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
D3015	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103</p> <p>A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, immunohematology records, and interview with the Laboratory Admin Director (LAD) and General Supervisor (GS) #7 (CMS 209), the laboratory failed to document all transfusion related activities performed on 11/02/2023, and 10/13/2022. Finding include: 1. The laboratory's Blood administration and Transfusion Reactions procedure states: "Record vital sign pre transfusion, at 15 minutes, then hourly until completion of transfusion. Vital signs will also be taken 1 hour post transfusion." 2. On the day of survey, 11/16/2023 at 9:07 am, review of the blood transfusion flow chart revealed the laboratory failed to document the following vitals for 2 of 4 patient reviewed that received a transfusion of red blood cells and had transfusion reactions: - Patient's vital signs after the transfusion reaction started for the event on 10/13/2022. -Missing stop time and 15 minutes vital sign pre transfusion for the event on 11/02/2023. 3. GS #7 confirmed the findings above on 11/16/2023 at 11:30 am.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's competency assessment records and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the laboratory failed to establish a competency assessment procedure to assess the competency of 5 of 6 technical consultant (TC) and 3 of 11 General Supervisor (GS) for their supervisory responsibilities performed in 2022 and 2023. Findings include: 1. The laboratory could not provide a competency assessment procedure to assess TS and GS for their supervisory responsibilities. 2. On the day of the survey, 11/14/2023 at 11:45 am, a review of laboratory's competency records revealed that the laboratory failed to perform a competency assessment for the 5 of 6 TC (CMS 209 TC #2, #3, #4, #5, #6) and 3 of 11 GS (CMS 209 GS #2, #3, and #4) for their supervisory responsibilities performed in 2022 and 2023. 3. The RD and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.

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 lack of documentation and interview with the Laboratory Director (LD) and Technical Supervisor #2 (TS), the laboratory failed to verify twice annually the accuracy of Hematology and Histopathology examinations performed in 2022 and 2023. Findings include: 1. On the days of survey, 11/14/2023 and 11/15/2023 the laboratory could not provide documentation of the bi-annual verification of accuracy for 2022 and 2023 for the following: - synovial crystals microscopic examinations. - grossing and inking macroscopic examinations. - Immunohistochemical (IHC) microscopic examinations. - Hematoxylin and Eosin (H&E) microscopic examinations. 2. LD and TS #2 confirmed the findings above on 11/15/2023 around 06:30 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) and the College of American Pathologist (CAP) proficiency testing (PT) records and interview with Technical Supervisor (TS) #2, the laboratory failed to document the evaluation and verification activities for PT testing performed in microbiology, chemistry, cytology, hematology/coagulation, and immunology/immunohematology from 09/17/2020 to the date of the survey. Findings Include: 1. On the day of the survey, 11/14/2023 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 in 2021: - 0% on Hematology/Coagulation 2021 3rd event: Andrology (Sperm Morphology glass/Image. -40% on Chemistry Core 2021 3rd event: Methemoglobin. 2. The laboratory could not provide documentation of the verification of accuracy for the following API PT events that were not graded by the PT testing agency: - 2021 Chemistry Core 2nd Event: Sweat analysis. -2021 Microbiology 3rd Event: Beta Lactamase, Cabapenemase, and Urine Culture MIC

/Zone Diameter Value -2021 Hematology/Coagulation 3rd Event: Vaginal Wet preparation (KOH), Sperm Classification, Antithrombin III activity. - 2021 Immunology/Immunoematology 3rd Event: Direct Antiglobulin test (DAT), compatibility tube testing. - 2022 Chemistry Core 1st Event: Procalcitonin, Sweat analysis, Body fluid Uric acid, Immunoassay special, tumor markers. - 2022 Microbiology 1st Event: CSF Culture MIC/Zone Diameter, CSF Culture Susceptibility interpretation, Urine Culture MIC/Zone Diameter Value, Gram Stain - 2022 Microbiology 2nd Event: Blood Culture MIC/Zone Diameter Value, Blood Culture Susceptibility Interpretation, Urine Culture MIC/Zone Diameter Value. - 2022 Immunology/Immunoematology 1st Event: Compatibility tube testing. - 2022 Hematology/Coagulation 1st Event: Sperm morphology. - 2022 Hematology /Coagulation 2nd Event: Antithrombin III activity, Vaginal Wet preparation, thromboelastogram, Urinalysis Bilirubin, Sperm morphology. -2022 Hematology /Coagulation 3rd Event: Blood Cell Identification, Antithrombin III activity, Sperm morphology. 3. The laboratory could not provide documentation of the verification of accuracy for the following CAP PT events that were not graded by the PT testing agency with codes 11, 26 and 27: - CAP F1-A 2022 Yeast: Antifungal - MIC Test (Code 27), Cryptococcal Titer (Code 26) - CAP F1-A 2022 Yeast: Antifungal - Agar Diff (Code 11), Cryptococcal Titer (Code 26) - CAP AQ-B 2002 Critical Care Blood Gas- Ionized Magnesium (Code 11) 4. The laboratory could not provide documentation of results reviewed by the LD and attestations for the proficiency testing performed for cytology for 1 of 2 events in 2022 and 2 of 2 events in 2023. 5. The laboratory could not provide documentation for proficiency testing for cytology for the second event in 2022. 6. TS #2 confirmed the findings above on 11/15/2023 around 06:15 PM. *CAP Code 11: Unable to analyze "Document why the specimens were not analyzed. Perform and document alternative assessment for the period that commercial PT was not tested." * CAP Code 26: Educational Challenge "Review participant summary for comparative results and document performance accordingly." * CAP Code 27: Lack of participant or referee consensus: "Document that the laboratory performed a self-evaluation and compared its results to the intend response when provided in the participant summary ..."

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory and interview with the Laboratory Admin Director (LAD) and General Supervisor (GS) #7 (CMS 209), the laboratory failed to ensure that reagents and supplies used for examinations in chemistry, microbiology, and immunoematology were not used beyond the expiration dates from 05/31/2022 to the date of the survey. Findings Include: 1. On the date of the survey, 02/07/2023 at 02:15 pm, the laboratory tour revealed that the following reagents and supplies used for chemistry, immunoematology, and microbiology examinations were expired: - Sure Vue Rotavirus Control - Lot # 305111, Expired 10/31/2023 - Rapid fFN Control - Lot E1025, Expired 05/31/2022 - Fentanyl Calibrator ARK- Lot 5031-0002-01, Expired 8/31/2023 - Reagent RED Blood Cell Panocell - Lot32630, Expired 10/13 /2023 - Reagent RED Blood Cell Panocell - Lot 34644, Expired 10/27/2023 2. The LAD and GS #7 confirmed the findings above on 11/16/2023 at 11:30 am.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the Advanced Instruments Model 3320 calibration records, and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the laboratory failed to perform calibrations on the Advanced Instruments Model 3320 analyzer used to perform Osmolarity tests from 07/11/2022 to the date of the survey. Findings Include: 1. The laboratory's Osmolarity Procedure states, "calibration is performed every 6 months." 2. On the day of the survey, 11/15/2023 at 11:51 am, review of the Advanced Instruments Model 3320 analyzer calibration records revealed the laboratory did not perform calibrations every 6 months as per their policy on the Advanced Instruments Model 3320 analyzer from 07/11/2022 to 11/15/2023. 3. The RD and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records and interview with the Regulatory Director (RD), Laboratory Admin Director (LAD), and Technical Supervisor (TS) (CMS 209 TS #2), the laboratory failed to document Hematoxylin and Eosin (H&E), and Immunohistochemical (IHC) QC monitoring activities for intended reactivity for histopathology slide examinations performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 10/14/2023 at 03:54 pm, review of the laboratory's QC records revealed the laboratory failed to document QC monitoring activities for intended reactivity each day of patient testing for histopathology slide examinations stained using H&E in 2022 and 2023. 2. The laboratory could not provide documentation of positive and negative reactivity each time of use for histopathology slide examination stained using IHC for 2022 and 2023. 3. The laboratory did not document lot and expiration date of the stain in QC

logs. 4. The laboratory performed 68022 pathology tests in 2022 (CMS 116 estimated annual test volume). 5. The RD, LAD and TS confirmed the finding above on 11/15 /2023 at 06:45 pm.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the cytotechnologist (CT), the cytology technical supervisor (CTS) failed to reassess workloads performed every 6 months for 2 of 2 testing personnel (TP) from 11/14/2021 to the day of survey.
Finding Include: 1. On the day of survey 11/14/2023 at 05:30 pm. the laboratory could not provide documentation for the reassessment of workloads every six months for 2 of 2 TP who performed cytology testing from 11/14/2021 to the day of survey. 2. The CT confirmed the finding above on 11/14/2023 around 6:45 pm.

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 lack of documentation and interview with the Regulatory Director (RD), Laboratory Admin Director (LAD), and General Supervisor (GS) #2 (CMS 209), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies for microbiology, hematology, and routine chemistry examinations performed in 2022 and 2023. Findings include: 1. On the days of survey, 11/15/2023, the laboratory failed to provide documentation of the biannual comparison studies performed in 2022 and 2023 for the following microbiology, hematology, and chemistry examinations: - Siemens Dimension Vista 1500 analyzers. - Human chorionic gonadotropin (hCG) testing performed on the Siemens Dimension Vista 1500 (quantitative) analyzer versus Cardinal hCG Combo Rapid Test: Serum (qualitative). - Body fluid cell count Sysmex XN 3000 versus manual microscopic. - GC molecular versus culture. - MRSA molecular versus culture. - ABO RH automated versus tube. - Antibody screen automated versus tube. - GBS PCR versus GB culture 2. The RD, LAD and GS #2 confirmed the findings above on 11/15/2023 at 06:45 pm.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or

both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's calibration records and interview with the Regulatory Director (RD), Laboratory Admin Director (LAD), and General Supervisor (GS) #2 (CMS 209), the laboratory failed to provide documentation of the corrective actions taken for calibration results that failed to meet the laboratory's established acceptable criteria for chemistry testing in 2023. Findings Included: 1. On the day of survey, 11/15/2023 at 11:48 am, review of the laboratory's calibration records revealed that the following calibration results for chemistry testing performed on the ADVIA Centaur XP failed to meet the laboratory's established acceptable criteria for the following analyte: - aHBs2 09/25/2023 Hepatitis B Surface antibody: status- Invalid. 2. The laboratory could not provide documentation of the corrective actions taken for calibration performed on the ADVIA Centaur XP that did not meet the laboratory's established acceptable criteria on 09/25/2023. 3. The RD, LAD and GS #2 confirmed the findings above on 11/15/2023 at 06:45 pm.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for chemistry, hematology, and microbiology test performed in 2022 and 2023. Findings Include: 1. On the day of the survey, 11/15//2023 at 01:03 pm, review of patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final reports for the following testing performed in 2022 and 2023. - Beta hCG Qualitative - Cortisol 60 Min - Paraneoplastic panel - Eos CSF - Cells Cnt Diff CSF - Group B Strep Ag - H Flu Type B Ag - N Men Grp A-Y Ag - S. pneumo Ag - VRE Vrq DNA - GBS DNA - MRSA DNA 2. The RD, and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on lack of documentation, competency record review, and interview with the

	<p>Regulatory Director (RD), and Laboratory Admin Director (LAD), the Technical Consultant (TC) failed to evaluate the competency assessment for 9 of 9 Testing Personnel (TP) who performed moderate complexity testing in mycology in 2022 and 2023. Findings include: 1. On the day of survey 11/14/2023 at 01:57 pm, the laboratory failed to provide competency assessment records for 9 of 9 TP (CMS 209 personnel #13, #16, #20, #21, #23, #25, #26, #27, #28) who performed Potassium hydroxide testing in mycology in 2022 and 2023. 2. The RD, and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the laboratory director (LD) failed to ensure that QC program was established and maintained to ensure the quality of services provided for testing performed in hematology, and urinalysis in 2022 and 2023. Findings Include: 1. On the days of the survey, 11/15/2023 at 02:15 pm, review of QC records revealed that the LD did not ensure that quality control programs were established and maintained for the following analytes in 2022 and 2023: -Casts and crystals -Microscopic Urinalysis. - Body Fluid crystal- Hematology - Urine Trichomonas- Urinalysis - Eosinophil slide examination 2. The RD, and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the laboratory Director (LD) failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the chemistry Sweat test performed in 2023. 1. On the day of the survey, 11/15/2023 at 12:42 pm, a review of sweat testing patient log revealed that sweat testing performed on the Wescor 3100 Sweat check analyzer by personnel who did not receive training or education for the following dates. - 4/22/23 -5/3/2023 2. During an interview, the RD stated the laboratory seized all operation on the sweat testing until everyone receive the necessary training on 11/15/2023 at 06:45 pm.</p>
<p>D6125</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES</p>

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency assessment records, and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the Technical Supervisor (TS) failed to assess the competency for 5 of 6 TP through external proficiency testing samples or internal blind testing samples for grossing or microscopic examinations in histopathology performed in 2022 and 2023. Findings include: 1. On the day of survey, 11/14/2023 at 11:53 am, review of histopathology TP competency assessment records revealed annual competencies performed in 2022 and 2023 did not include the assessment of external proficiency testing samples or internal blind testing samples for 5 of 6 TP (CMS 209 TP # 2, #3, #4, #5, #6, and #7) who performed grossing or microscopic examinations in histopathology in 2022 and 2023. 2. The RD and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on lack of documentation, competency record review, and interview with the Regulatory Director (RD), and Laboratory Admin Director (LAD), the Technical Supervisor (TS) failed to evaluate the competency assessment for 9 of 9 Testing Personnel (TP) who performed testing in microbiology in 2022 and 2023. Findings include: 1. On the day of survey 11/14/2023 at 01:57 pm, the laboratory failed to provide competency assessment records for 9 of 9 TP (CMS 209 personnel #13, #16, #20, #21, #23, #25, #26, #27, #28) who performed following examinations in microbiology in 2022 and 2023. -Blood Culture -Anaerobic Culture - Body Fluid Culture - E Coli 0157/Shiga stool - Salmonella/Shigella stool culture - Yersinia Culture stool - Ear Culture -Ear Culture -Genital Culture -Respiratory Culture - Sputum Culture -Nasal Culture -Throat Culture -Tissue Culture -Yeast ID -Aerobic ID -Sensitivities 2. The RD, and LAD confirmed the findings above on 11/15/2023 at 06:45 pm.