Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0181725	(X3) Date Survey Completed 10/22/2025
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 routine recertification survey was conducted by the Pennsylvania State Agency for Penn Highlands Dubois on 10/21/2025 and 10/22/2025. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic Systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #3, the laboratory failed to monitor and document temperature and humidity to ensure reagent storage requirements were met as per PA regulations when 1 of 1 chemistry test (Whole Blood Glucose) was performed from 11/16/2023 to 10/22/2025. Findings include: 1. On the day of the survey, 10/22/2025 at 1:00 pm, review of the laboratory's Accu-Chek Inform Blood Glucose Determination policy stated, " Store the strips at room temperature at 59 to 86 degrees Fahrenheit (15 to 30 degrees Celsius)." 2. The laboratory failed to provide documentation for the monitoring of temperatures to ensure reagent storage requirements for the Accu-Chek Inform Blood Glucose strips were met for 1 of 1 chemistry test (Whole Blood Glucose) performed in the point of care areas from 11/16/2023 to 10/22/2025. 3. TS #3 confirmed the findings above on 10/22/2025 at 2:00 pm.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #3, the laboratory failed to retain weekly microbiology susceptibility quality control (QC) records for 23 of 24 months as required from 11/16/2023 to 10/21/2025. Findings include: 1. On the day of survey, 10/21/2025 at 11:30 am, review of laboratory microbiology weekly QC records and interview with TS #3 revealed that only cumulative microbiology chart reports for susceptibility QC are retained by the laboratory. 2. The laboratory failed to provide the individual microbiology chart reports for QC organism testing performed for 23 of 24 months from 11/16/2023 to 10/21/2025. 3. TS#3 confirmed the findings above on 10/22/2025 at 1:15 pm.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) (a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with General Supervisor (GS) #1 , the laboratory failed to retain chemistry quality system assessment records for 23 of 24 months as required from 11/16/2023 to 10/21/2025. Findings include: 1. On the day of survey, 10/21/2025 at 12:30 pm, review of laboratory policy titled Daily Surveillance of Results stated, "Daily Exception and Correction reports are reviewed by Supervisor or delegate". 2. The laboratory failed to provide documentation of the exception and correction reports reviewed by the supervisor or delegate for 23 of 24 months from 11/16/2023 to 10/21/2025. 3. GS #1 confirmed the findings above, on 10/21/2025 at 1:15 pm, and stated "the exception /correction reports are only kept for 30 days".
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, and interview with General Supervisor (GS) #3, the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 from 11/16/2023 to date of survey. Refer to D5413, D5415, D5417, D5423, D5429, D5439, D5445, D5601, D5775, and D5783.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: A. Based on lack of documentation and interview with Technical Supervisor (TS) #3, the laboratory failed to monitor the humidity of the laboratory to ensure proper operating conditions were met for 8 of 8 laboratory areas where microbiology, hematology (urinalysis), histopathology, cytology, chemistry (blood gas), coagulation, immunology, and immunohematology testing was performed from 11/16/2023 to 10/1/2025. Findings include: 1. On the day of survey, 10/21/2025, at 10:00 am, the laboratory failed to provide documentation of humidity monitoring for 8 of 8 laboratory areas to ensure operating conditions were met where microbiology, hematology (urinalysis), histopathology, cytology, chemistry (blood gas), coagulation, immunology, and immunohematology testing was performed from 11/16/2023 to 10/1/2025. 2. The laboratory performed 2,058,783 total tests/examinations in 2024 (CMS 116,estimated annual volume, dated 10/1/2025). 3. TS #3 confirmed the findings above on 10/21/2025 at 12:30 pm. B. Based on observation in the laboratory, review of laboratory temperature records, and interview with General Supervisor (GS) #5, the laboratory failed to monitor room temperatures to ensure acceptable reagent storage temperatures were maintained on weekends and holidays for 481 of 708 days from 11/16/2023 to 10/22/2025. Findings include: 1. On the day of survey, 10/22/2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Dako Artisan Wash Solution. Storage requirements 15C to 30C. - Cardinal Health Formalin. Storage requirements 15C to 30C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures to ensure acceptable reagent storage temperatures were maintained for 481 of 708 days from 11/16/2023 to 10/22/2025 when the laboratory was closed. 3. GS #5 confirmed the findings above on 10/22/2025 at 11:45 am. C. Based on observation in the laboratory, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to monitor daily temperatures and humidity to ensure proper operating conditions were met for 3 of 3 Olympus microscopes used to perform microscopic histopathology and cytology examinations from 11/16/2023 to 10/22/2025. 1. Review of the manufacturer's instructions revealed the following acceptable operating temperature and humidity range for the Olympus BX 53, BX45, and DP72 microscopes: - Temperature 5C to 40C - Humidity 0 to 80% Relative Humidity 2. On the day of the survey, 10/22/2025 at 11:15 am, the laboratory failed to provide temperature and relative humidity documentation to ensure proper operating conditions were met for 3 of 3 Olympus microscopes used to perform microscopic histopathology and cytology examinations from 11/16/2023 to 10/22/2025. 3. The LD confirmed the findings above on 10/22/2025 at 11:30 am.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations of the laboratory and interview with General Supervisors (GS) #3 and #5, the laboratory failed to label 4 of 4 aliquoted reagents with the pertinent information required for proper use when manual stain examinations were performed from 11/16/2023 to 10/21/2025. Findings Include: 1. On the day of survey, 10/22 /2025 at 11:30 am, during the laboratory tour, observation of the hematology and histology departments revealed 4 of 4 containers used to aliquot manual staining reagents were not properly labeled with the following when manual stain examinations were performed from 11/16/2023 to 10/21/2025: - Identity of reagent - Storage requirements - Preparation and expiration dates 2. GS#3 and GS#5 confirmed the findings above on 10/22/2025 at 3:46 pm.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 General Supervisor (GS) #3, the laboratory failed to ensure that 2 of 3 reagents used to prepare microscopic hematology differential slides were not used beyond the expiration dates from 5/31/2023 to date of survey. Findings include: 1. On the day of the survey, 10/22 /2025 at 11:56 am, observation during the laboratory tour revealed the following 2 of 3 expired reagents currently being used to prepare manual microscopic hematology differential slides from 11/16/2023 to 10/22/2025: - 1 opened bottle of Three step solution B (Lot #142352, expired 5/10/2025). - 1 opened bottle of Three step solution A (Lot # 118847, expired 5/31/2023). 2. The laboratory performed 979 manual microscopic hematology differential examinations from 11/14/2024 to 10/21/2025. 3. GS#3 confirmed the findings above on 10/22/2025 at 2:35 pm. **Repeat deficiency**
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values).

	(b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #3, the laboratory failed to establish and verify performance specifications before reporting patient test results when modifying an FDA-cleared /approved test system for body fluid (BF) chemistry examinations performed on 2 of 2 Siemens Vista chemistry analyzers from 11/16/2023 to 10/21/2025. Findings include: 1. On the day of survey, 10/21/2025 at 10:45 pm, review of the Siemens Vista procedures revealed the laboratory performed the following chemistry tests on 2 of 2 Siemen's Vista chemistry analyzers using BF specimens from 11/16/2023 to 10/21 /2025. -Albumin (Alb) -Amylase (Amy) -Bilirubin (Bili) -Cholesterol (Chol) -Creatinine (Cre) -Glucose (GLU) -Lactate dehydrogenase (LDH) -Total Protein (TP) -Triglyceride (Trig) -Urea Nitrogen (BUN) -Uric Acid (UA) 2. Further review of the Siemens Vista manufacturer's instructions for use revealed the following: -Alb: "Recommended specimens: serum and plasma(lithium and sodium heparin). " -Amy: "Recommended specimen types: serum and plasma (lithium heparin) and urine." -Bili: "Recommended specimen types: serum and plasma (lithium heparin and EDTA)." -Chol: "Recommended specimen types: serum and plasma (lithium heparin)." -Cre: "Recommended specimen types: serum and plasma (lithium heparin) and urine." -Glu: "Recommended specimen types: serum, plasma(lithium heparin, sodium heparin, and sodium fluoride), urine and CSF." - LDH: "Recommended specimens: serum and plasma(lithium and sodium heparin). " - TP: "Recommended specimen types: serum and plasma (lithium heparin)." -Trig: "Recommended specimen types: serum and plasma (lithium heparin)." -BUN: "Recommended specimen types: serum and plasma (lithium heparin) and urine." -UA: "Recommended specimen types: serum and plasma (lithium heparin) and urine." 3. The laboratory failed to provide documentation for the performance specifications established and verified when performing BF chemistry examinations on 2 of 2 Siemen's Vista chemistry analyzers from 11/16/2023 to 10/21 /2025. 4. TS #3 confirmed the findings above on 10/21/2025 at 1:30 pm. B. Based on record review, lack of documentation, and interview with General Supervisor (GS) #3, the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for platelet count (PLT) examinations performed on 2 of 2 Sysmex XN3000 hematology analyzers using sodium citrate anticoagulant from 11/16/2023 to 10/21/2025. Findings include: 1. Review of the Sysmex XN 3000 manufacturer's instructions for use stated, "Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended." 2. On the day of the survey, 10/21/2025 at 02:15 pm, the laboratory failed to provide documentation for the performance specifications established when performing PLT counts using sodium citrate anticoagulant (blue top tube) on 2 of 2 Sysmex XN3000 hematology analyzers from 11/16/2023 to 10/21/2025. 3. GS #3 confirmed the findings above on 10/21/2025 at 4:30 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on lack of maintenance records, and interview with the Administrative Director (AD), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 3 of 3 traceable thermometers used to ensure acceptable storage and operating temperatures were met in the hematology /urinalysis departments from 01/01/2024 to 12/31/2024. Findings include: 1. The laboratory failed to provide documentation of maintenance and function checks performed for the following 3 of 3 traceable thermometers used to monitor refrigerator, room, and heat block temperatures in the hematology/urinalysis departments for 2024: - Room Temperature thermometer (s/n 42573) - Heat block thermometer (s/n 4285) - Refrigerator thermometer (s/n 22221) 2. The AD confirmed the above findings on 10/22/25 at 3:00 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 on review of calibration verification (Cal Ver) records and interview with General Supervisor (GS) #1, the laboratory failed to perform calibration verification at least every six months as required for 2 of 2 Siemens Dimension Vista 1500 routine chemistry analyzers from 11/14/2023 to 10/21/2025. Findings include: 1. On the date of survey, 10/21/2025 at 11:00, review of laboratory records for Cal Ver revealed the laboratory failed to ensure the calibration verifications for 2 of 2 Siemens Dimension Vista 1500 chemistry analyzers were performed at least every 6 month for the following from 11/16/2023 to 10/21/2025. - Siemnens Dimension Vista 1500 (1): Cal Ver performed: February 2024-December 2024 (10 months) - Siemnes Dimension Vista 1500 (2): Cal Ver performed: 2/2024-12/2024 (10 months) 12/2024-8/2024 (8 months) 2. GS #1 confirmed the finding above on 10/21/2025 at 1:00 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with General Supervisor (GS) #6, the laboratory failed to perform QC procedures as required for activated clotting time (ACT) testing performed on 9 of 9 ITC Hemochron Signature Elite analyzers and hemostasis testing performed on 2 of 2 Haemonetics TEG 6s analyzers at least once each day of patient testing from 11/16/2023 through the date of survey. Findings include: 1. On the day of survey, 10/21/2025 at 03:00 pm, review of the laboratory's QC records revealed the laboratory failed to ensure QC was performed at least once each day of testing for the following tests from 11/16/2023 to 10/21/2025: - ACT: 9 of 9 ITC Hemochron Signature Elite (SN 3360, 19905, 21647, 21648, 3591, 3570, 3927, 21683, 22235) - TEG Global Hemostasis/Platelet Mapping: 2 of 2 Haemonetics TEG 6s (SN T1-18E0101120 and T1-18E-101121) 2. Further review of QC records revealed the laboratory performed external QC for ACT and hemostasis testing monthly. The laboratory failed to provide an Individualized Quality Control Plan (IQCP). 3. GS #6 confirmed the findings above on 10/21/2025 at 03:30 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with General Supervisor (GS) #5, the laboratory failed to ensure positive and negative staining reactivity was checked and documented each time of use when immunohistochemical (IHC) stains for microscopic histopathology examinations were performed for 2 of 2 years from 11/16/2023 to 10/22/2025. Findings include: 1. On the day of the survey, 10/22/2025 at 10:00 am, review of the laboratory's QC records revealed the laboratory failed to document the positive and negative staining reactivity checked each time of use when IHC stains for microscopic histopathology examinations were performed for 2 of 2 years from 11/16/2023 to 10/21/2025. 2. GS #5 confirmed the findings above on 10/22/2025 at 12:30 pm. **Repeat Deficiency**
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. This STANDARD is not met as evidenced by: A. Based on record review, lack of documentation, and interview with General Supervisor (GS) #2, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments for 2 of 2 Siemens Dimension Vista 1500 chemistry analyzers used to perform routine chemistry testing in 2025. Findings include: 1. On the day of the survey, 10/21/2025 at 11:30 am, the laboratory failed to provide documentation to evaluate the relationship between different chemistry methodologies/instruments performed for 2 of 2 Siemens Dimension Vista 1500 (SN DV31145 and DV350105) used for routine chemistry examinations in 2025. 2. GS # 1 confirmed the findings above on 10/21/2025 at 1:00 pm. B. Based on record review, lack of documentation, and interview with General Supervisor (GS) #3, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments for 2 of 2 Sysmex XN 3000 hematology analyzers used from 11/16/2023 to 10/21/2025. Findings include: 1. On the day of the survey, 10/21/2025 at 01:30 pm, the laboratory failed to provide documentation for the evaluation performed twice a year for 2 of 2 Sysmex XN 3000 analyzers (XN 14182 and XN14167) to monitor and evaluate the relationship between methodologies/instruments used for the following hematology examinations performed from 11/16/2023 to 10/21/2025: - EDTA vs Sodium Citrate tubes for Platelets 2. GS # 3 confirmed the findings above on 10/21/2025 at 03:30 pm. **Repeat Deficiency**
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 record review, lack of documentation, and interview with General Supervisor (GS) #8 , the laboratory failed to ensure corrective action was taken to ensure reliable patient test results were reported for Oxyhemoglobin (O2Hb) examinations performed on 1 of 1 RapidPoint 500e blood gas analyzer when quality control (QC) failed to meet the laboratory's criteria for acceptability on 07/01/2024. Findings Include: 1. On the day of survey, 10/21/2025 at 12:15 pm, review of the laboratory's July 2024 QC results revealed O2Hb QC level III results for 07/01/2024 failed to meet the laboratory's established acceptable limits. 2. The laboratory failed to provide documentation for the corrective action taken for O2Hb examinations performed on 1 of 1 RapidPoint 500e blood gas analyzer when QC failed to meet the laboratory's acceptable criteria on 07/01/2024. 3. GS #8 confirmed the above findings on 10/21/2025 at 12:45 pm. ** Repeat Deficiency**
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Technical Supervisor (TS) #2, the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 2 of 2 years from 11/16/2023 to 10/22/2025. Findings include: 1. On the day of survey, 10/22/2025 at 12:15 pm, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correct problems found in the postanalytic system specified in 493.1291 for 2 of 2 years from 11/16/2023 to 10/22/2025. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (LIS) from 11/16/2023 to 10/22/2025: - Patient results transmitted between instruments and LIS - Patient Specific data. 3. TS #2 confirmed the findings above during interview on 10/22/2025 at 12:50 pm; TS #2 stated "the laboratory did not have a process in place to monitor and evaluate the accuracy of information provided to the client."
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 record review and interview with Technical Supervisor (TS) #3, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 11/16/2023 to 10/22/2025. Refer to D6086, D6091, D6093, D6103, and D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of the RapidPoint 500e analyzer validation records and interviews with General Supervisor (GS) #8 and Technical Supervisor (TS) #3, the Laboratory Director (LD) failed to ensure that the performance specification procedures used to determine the accuracy, precision, reportable range, and reference range for Blood Gas testing performed on 1 of 1 RapidPoint 500e analyzer were adequate before reporting patient test results from 5/1/2024 to 10/21/2025. Findings Include: 1. On the day of survey, 10/21/2025 at 9:30 am, review of the RapidPoint 500e validation records revealed that the validation performed in May 2024 was not reviewed or

	approved by the LD prior to reporting patient test results for blood gas examinations performed on 1 of 1 RapidPoint 500e analyzer from 5/1/2024 to 10/21/2025. 2. TS #3 confirmed the findings above on 10/21/2025 at 12:30 pm. .
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on policy and proficiency testing (PT) result review, and interview with Technical Supervisor (TS) #3, the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 10 of 10 testing events from 11/16/2023 to 10/21/2025. Findings include: 1. On the day of survey, 10/21/2025, at 9:50 am, review of the Laboratory's policy titled, Proficiency Testing, revealed the policy stated, "The appropriate testing personnel and supervisor conducts an investigation and retains all documentation of all potential causes, provides evidence of review, and performs corrective action for the following: *Individual unacceptable proficiency testing results (less than 100%) *Late submissions of proficiency testing results (score is zero) * Nonparticipation in the proficiency testing event (score is zero)*Lack of nonconsensus among all laboratories participating in the proficiency testing event (score is ungradable)." 2. Review of the laboratory's American Proficiency Institute (API) and College of American Pathologists (CAP) PT testing reports revealed the LD failed to ensure the following PT testing events were reviewed and evaluated by the appropriate staff to identify problems that required corrective action when results for the following 7 of 10 PT testing events were ungraded by the PT agency from 11/16 /2023 to 10/21/2025: - 2024 API 2024 Hematology/Coagulation 3rd Event -Body Fluid Cell Count: BFC-03 - Body Fluid Crystals: CYS-03 - Sperm Classification: SCL-13, SCL-14, SCL-18, SCL-19, SCL-20 - 2025 API Hematology/Coagulation 1st Event: - Body Fluid Crystals: CYS-02 - Sperm Classification: SCL-04, SCL-06, SCL-07, SCL-08 - 2024 API Microbiology 1st Event - CSF Bacterial Antigen: N. meningitis: CBA-01. CBA-02 - CSF Culture MIC/ZONE Diameter Value: MIC Vitek 2: SF-01 - CSF Culture Susceptibility Interpretation: MIC testing: SF-01 - GC/Group B Strep Culture: Group B Strep Culture: GC-05 - Gram Stain: GS-02 - Stool Culture: SC-01 - Urine Culture MIC: UR-01 - 2024 API Hematology/Coagulation 1st Event: - Body Fluid Crystals: CYS-02 - Sperm Morphology: Sperm Classification: SCL-05, SCL-08, SCl-10 - Thromboelastogram: TG-01, TG-02, TG-03 - 2024 CAP PLTM-A Platelet Mapping: - ADP: PLTM01, PLTM-02 - 2024 CAP PLTM-B Platelet Mapping: - ADP: PLTM-03, PLTM-04 - 2025 CAP CD30-A CD30 Immunohistochemistry, Tissue Mircoarray: - JCM182: CD-30-01 3. Further review of the laboratory's CAP and API PT results revealed the laboratory failed to perform corrective action for the following 5 of 10 PT results when the laboratory received an unacceptable grade from the PT agency from 11/16/2023 to 10/2025: - 2025 CAP CD-30A:CD-30 Immunohistochemistry: Core 09-% staining - 2025 CAP P16-A 2025: P16 Immunohistochem Tissue Microar: Core 3 - 2025API Chemistry-Core-2nd Event: Vancomycin: CH-10 - 2025 API Chemistry-Core-1st Event: Vancomycin: CH-03 - 2024 API Hematology/Coagulation-3rd Event: Sperm Motility %: MOT-03 4. TS #3 confirmed the findings on 10/22/2025 at 11:30 am.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 lack of documentation and interview with Technical Supervisor (TS) #3, the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established, maintained, and documented to ensure the quality of services provided by 7 of 8 laboratory departments from 11/16/2023 to 10/22/2025. Findings include: 1. On the date of the survey, 10/22/2025 at 10:00 am, the laboratory failed to provide complete documentation for the QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 7 of 8 departments from 11/16/2023 to 10/22/2025: Histopathology, Cytopathology, Hematology, Chemistry, Coagulation, Microbiology, and Immunology. 2. TS #2 confirmed the findings above on 10/22/2025 at 11:30 am.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 review of personnel competency assessment records and interview with technical supervisor (TS) #3, the Laboratory Director (LD) failed to ensure that procedures were established and maintained to ensure 31 of 68 testing personnel (TP) who conduct preanalytical, analytical, and postanalytical phases of testing were competent and maintained their competency from 11/16/2023 to day of the survey. Findings Include: 1. On the day of the survey, 10/22/2025 at 10:30 am, review of the laboratory's personnel competency assessment records revealed the LD failed to ensure procedures were established and maintained to ensure 31 of 68 TP that performed the following testing were competent and maintained their competency from 11/16/2023 to 10/22/2025: - Activated Clotting Time (ACT) - Thromboelastography (TEG) 2. The laboratory failed to provide documentation for the assessment of competency for 4 of 68 TP that performed the following testing for the minimal regulatory requirements (6 CLIA required competency procedures): - Semen analysis - Herpes - Macroscopic and microscopic tissue examinations 3. TS#3 confirmed the findings above on 10/22/2025 at 12:15 pm.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with Technical Supervisor (TS) #3, the laboratory director (LD) failed to ensure approved chemistry policies were available to testing personnel for 2 of 2 years from 11/16/2023 to 10/21 /2025. Findings Include: 1. On the day of survey, 10/21/2025 at 10:30 am, review of the laboratory's current procedure manual revealed the LD failed to ensure an approved policy for the operation of the Siemens Vista and Centaur chemistry analyzers were available to testing personnel for 2 of 2 years when chemistry testing was performed from 11/16/2023 from 10/21/2025. 2. TS#3 confirmed the findings on 10/21/2025 at 11:00 am.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #3, the TS failed to provide overall management and direction of the laboratory in accordance with 493.1451 from 11/16/2023 to 10/22/2025. Refer to D6112, D6122, D6123, and D6125.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of procedures, patient reports, and interview with Technical Supervisor (TS) #3, the TS failed to ensure 2 of 2 patient reports for macroscopic histopathology examinations (grossing and inking) that were performed in the absence of the TS by delegated testing personnel (TP) qualified under 493.1489 were reviewed within 24 hours from 11/16/2023 to 10/22/2025. Findings include: 1. On the day of survey, 10/22/2025 at 10:00 am, review of the laboratory's Gross Surgical Specimens (Examination & Dictating) procedure stated, "C. The performance of the non-pathologist will be evaluate by the pathologist in the following manner: -The pathologist will supervise the non-pathologist designated function and will be available for questions pertaining to the gross tissue examination. -The non-pathologist gross tissue examination will be indirectly evaluated within 24 hours and the comment "A pathologist has reviewed the gross analysis and is satisfactory" will be included on the Surgical Pathology Report. -The pathologist will annually assess and document the competency of the non-pathologist. " 2. The laboratory failed to provide documentation that the review of macroscopic gross examinations performed by non-pathologists was completed within 24 hours as outlined by policy for 2 of 2

	patient test reports reviewed from 11/16/2023 to 10/22/2025. 3. TS #3 confirmed the findings above on 10/22/2025 at 1:30 pm.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) (b)(8)(ii) Monitoring the recording and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals, lack of documentation, and interview with Technical Supervisor (TS) #3, the TS failed to assess the competency of 10 of 10 testing personnel (TP) for monitoring the recording and reporting of test results of macroscopic histopathology examinations performed from 11/16/2023 and 10/22/2025. Findings Include: 1. On the day of survey, 10/22/2025, at 11:30 am, review of the policy titled "Laboratory Competency Assessment Plan" stated, "Six (6) procedures are used for regulatory competency assessment of all testing personnel: 1. Direct observation of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observations of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: and 6. Assessment of problem solving skills. " 2. The laboratory failed to provide competency assessment documentation for monitoring the recording and reporting of test results for 10 of 10 TP (CMS 209 TP #1,2,3,4,5,6,7,8,9, and #10, dated 10/21/2025) for macroscopic histopathology (grossing and inking) performed from 11/16/2023 to 10/22/2025. 3. TS #3 confirmed the findings above on 10/22/2025 at 12:30 pm.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals, lack of documentation, and interview with Technical Supervisor (TS) #3, the TS failed to to assess the competency 10 of 10 testing personnel (TP) for review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for macroscopic histopathology examinations performed from 11/16/2023 to 10/22/2025. Findings Include: 1. On the day of survey, 10/22/2025, at 11:30 am, review of the policy titled "Laboratory Competency Assessment Plan" stated, "Six (6) procedures are used for regulatory competency assessment of all testing personnel: 1. Direct observation of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observations of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing

	previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: and 6. Assessment of problem solving skills. " 2. The laboratory failed to provide competency assessment documentation for the review of test results or worksheets, quality control records, proficiency testing results,or preventative maintenance records for 10 of 10 TP (CMS 209, TP #1,2,3,4,5,6,7,8,9 and #10) that performed macroscopic histopathology (grossing and inking) examinations from 11/16 /2023 to 10/22/2025. 3. TS #3 confirmed the findings above on 10/22/2025 at 12:30 pm.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals, lack of documentation, and interview with Technical Supervisor (TS) #3, the TS failed to to assess the competency of 10 of 10 testing personnel (TP) for the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for macroscopic histopathology examinations performed from 11/16/2023 to 10/22/2025. Findings Include: 1. On the day of survey, 10/22/2025, at 11:30 am, review of the policy titled "Laboratory Competency Assessment Plan" stated, "Six (6) procedures are used for regulatory competency assessment of all testing personnel: 1. Direct observation of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observations of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: and 6. Assessment of problem solving skills. " 2. The laboratory failed to provide competency assessment documentation for the assessment of test performance through testing of previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for 10 of 10 TP (CMS 209, TP #1,2,3,4,5,6,7,8,9 and #110) that performed macroscopic histopathology (grossing and inking) examinations from 11/16/2023 to 10/22/2025. 3. TS #3 confirmed the findings above on 7/24/2025 at 12:30 pm *Repeat deficiency