Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0185151	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ph Dubois, Clearfield Campus	809 Turnpike Avenue, Clearfield, 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
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 laboratory procedure manuals, lack of documentation, and interview with Technical Supervisor (TS) #3, the laboratory failed to follow established policy's to assess the competency of 1 of 8 technical consultants (TC) for their supervisory duties performed (493.1413) in 2024 and 2025. Findings Include: 1. On the day of survey, 7/24/2025, at 11:30 am, review of the policy titled "Laboratory Competency Assessment Plan" stated, "In addition to completing and maintaining annual competency as testing personnel, titled Laboratory Supervisors and Director must also complete and maintain annual competency for these duties. Supervisory Competency Review and Observation of: 1. Available for Consultation to Laboratory Staff. 2. Proficiency Testing - enrollment confirmed for current year, ongoing participation and review of proficiency testing results with corrective action as necessary. 3. Quality Control Program - secondary review of all quality control results for each test system completed confirming test system is functioning properly and corrective actions were taken and documented as needed. 4. Laboratory Personnel Training and Competency - training completed and documented for all new staff, competency assessments and remedial training completed, as needed, for all testing personnel using the six regulatory requirements for assessment of competency noted above. 5. Annual Personnel Performance Evaluations - performance evaluations completed for each staff member annually. 6. Departmental Procedure Manuals - manuals of responsibility reviewed and revised annually." 2. The laboratory failed to

	provide competency assessment documentation for 1 of 8 TC (Form CMS 209, TC #7, dated 07/03/2025) for 2024 and 2025. 3. TS #3 confirmed the findings above on 7 /24/2025 at 12:30 pm.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Supervisor #3 (TS), the laboratory failed to verify the accuracy of the PT results obtained for 9 of 16 API PT Performance Evaluation reports reviewed for chemistry, hematology, immunology, and microbiology testing performed from 07/13/2023 to the date of the survey. Findings Include: 1. The API Proficiency Testing performance Evaluation form stated "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. On the day of survey, 07/23 /2025 at 1:45 pm, review of the laboratory's API PT Performance Evaluation records revealed the laboratory failed to verify the accuracy or perform a self-evaluation for analytes that were not graded by the PT agency for the following 9 of 16 API PT Performance Evaluation reports reviewed onsite for chemistry, hematology, immunology and microbiology testing performed from 07/13/2023 to 07/23/2025: API 2024 Microbiology-1st Event: - Additional Antimicrobial Testing: ESBL (ES-01) - CSF Culture MIC/Zone Diameter Value (SF-01) - CSF Culture Susceptibility Interpretation (SF-01) - Gram Stain Morphology (GS-02) - Respiratory Panel: QIAstat-Dx Resp SARSCoV2 Panel Influenza A (RSP-01) - Urine Culture MIC/Zone Diameter Value (UR-01) - Urine Culture Susceptibility Interpretation (UR-01) API 2024 Microbiology 2nd event: - Blood Culture MIC/Zone Diameter Value (BL-01) - Blood Culture Susceptibility Interpretation (BL-01) - Urine Culture MIC/Zone Diameter Value (UR-06) - Urine Culture Susceptibility Interpretation (UR-06) API 2024 Immunology/Immunohematology 1st event: - C-reactive Protein (CRP-02) API 2024 Hematology/Coagulation 1st Event: - Body Fluid Crystals (CYS-02) API 2024 Hematology/Coagulation 3rd Event: - Automated Urine Microscopy-S (UMS-03) - Body Fluid Crystals (CYS-03) - Urinalysis & HCG: Bilirubin (UA-06) API 2024 Chemistry-Core 1st Event: - Chemistry: ALT/SGPT (CH-04) API 2024 Chemistry-Core 2nd Event: - Chemistry: Iron (CH-08) API 2025 Hematology/Coagulation 1st Event: - Body Fluid Crystals (CYS-02) - Gastric Occult Blood: Gastric pH (GOB-02) - Urine Eosinophils (UE-01) API 2025 Microbiology 1st Event: - Urine Culture A-Microzone Diameter (UR-01) 3. TS #3 confirmed the findings above on 07/23/2025 at 04:00 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 Histotechnologist (HT), the laboratory failed to ensure the verification of accuracy for macroscopic histopathology examinations were performed at least twice annually, as required for 1 of 1 test not included in subpart I from 7/12/2023 to 7/24/2025. Findings include: 1. On the day of survey, 07/24/2025 at 9:30 am, the laboratory failed to provide documentation for the verification of accuracy performed for macroscopic histology examinations at least twice annually from 7/12/2023 to 7/24/2025. 2. The laboratory failed to provide a policy for verification of accuracy for macroscopic histology examinations. 3. The laboratory reported an annual volume of 5603 examinations/tests performed in Histopathology (CMS 116 estimated annual volume for 2024). 4. The HT confirmed the above findings on 7/24/2025 at 9:45 am.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Supervisor #3 (TS), the laboratory failed to document the evaluation and verification activities for 1 of 3 2024 API PT Performance Evaluation reports reviewed for immunology (syphilis) testing performed in 2024. Findings Include: 1. On the day of the survey, 07/23/2025 at 01:45 pm, review of the laboratory's 2024 API Immunology/Immunohematology PT Performance Evaluation reports revealed the laboratory received an unacceptable performance for the following immunology testing performed for 1 of 3 API PT events performed in 2024: - 2024 API Immunology/Immunohematology- 1st Event: Syphilis (titer, serum) specimen SYP-03. 2. The API PT Performance Evaluation report stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or "not graded" analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. The laboratory failed to provide documentation for the corrective action taken for unacceptable performance received for 2024 API Immunology/Immunohematology- 1st Event: Syphilis (SYP-03). 4. TS #3 confirmed the findings above on 07/23/2025 at 03:00 PM.
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:

	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 7 of 7 laboratory areas in the laboratory where microbiology, hematology, histopathology, chemistry (urinalysis/blood gas), and immunohematology testing was performed from 7/12/2023 to 7/24/2025. Findings include: 1. On the day of survey, 7/24/2025, at 10:00 am, the laboratory failed to provide documentation of humidity monitoring for 7 of 7 laboratory areas where microbiology, hematology, histopathology, chemistry (urinalysis/blood gas), and immunohematology testing was performed from 7/12/2023 to 7/24/2025. 2. The laboratory performed 1,086,040 total tests/examinations in 2024 (CMS 116,estimated annual volume, dated 07/15/2025). 4. TS #3 confirmed the findings above on 7/24 /2025 at 12:30 pm.
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 7/12/2023 to 7/23/2025. Findings include: 1. On the day of survey, 7/23/2025 at 12:45 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 7/12/2023 to 7/23/2025. - Amylase (Amy) -Glucose (GLU) -Total protein (TP) -Lactate dehydrogenase (LDH) 2. Further review of the Siemens Vista manufacturer's instructions for use revealed the following: - Amy: "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." - TP: "Recommended specimen types: serum and plasma (lithium heparin)." - LDH: "Recommended specimens: serum and plasma(lithium and sodium heparin). " 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 7/12//2023 to 7/23/2025. 4. TS #3 confirmed during interview on 07/23 /2025 at 1:30 pm the laboratory reported the following patient test results on BF samples from 07/12/2023 to 07/23/2025: BF Amy - 6 examinations BF Glu- 6 examinations BF TP - 9 examinations BF LDH - 12 examinations 5. TS #1 confirmed the findings above on 7/23/2025 at 1:30 pm. B. Based on record review, lack of documentation and interview with Technical Supervisor (TS) #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 XN hematology analyzers using sodium citrate anticoagulant from 7/12/2023 to 7/23/2025. Findings include: 1. Review of the Sysmex XN 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, 07 /23/2025 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 XN hematology analyzers from 7/12/2023 to 7/23/2025. 3. TS #3 confirmed the findings above on 7/23/2025 at 4:30 pm.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on record review, observation of the laboratory, and interview with Technical Supervisor #3 (TS), the laboratory failed to ensure an audible alarm system monitored proper blood and blood product storage temperatures over a 24-hour period for 1 of 1 chest freezer used for the storage of blood products from 03/21/2025 to the date of the survey. Findings Include: 1. On the day of survey, 07/25/2025 at 11:30 am, during the tour of the laboratory 1 of 1 chest freezer with no audible alarm system was observed being used for the storage of the following blood products: - 11 units of fresh frozen plasma (FFP) - 2 units of cryoprecipitate (cryo) 2. Review of the laboratory's Chest Freezer Temp- Monitoring FFP temperature logs revealed the chest freezer was used for the storage of blood products from 03/21/2025 to the date of the survey. 3. TS #3 confirmed the findings above on 07/24/2025 at 12:00 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. 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 evaluate twice a year the relationship between test results using different methodologies and instruments for 4 of 4 comparison studies performed for hematology and chemistry methodologies /instrumentation used from 7/12/2023 to 7/24/2025. Findings include: 1. On the day of the survey, 7/24/2025 at 11:30 am, the laboratory failed to provide documentation for the evaluation performed twice a year (4 of 4 comparison studies) to monitor and

	evaluate the relationship between methodologies/instruments used for the following hematology examinations performed from 07/12/2023 to 07/24/2025: - EDTA vs Sodium Citrate tubes for Platelets on 2 of 2 Sysmex XN analyzers - Nucleated Red Blood Cells on 2 of 2 Sysmex XN analyzers - Manual and automated differential (Sysmex XN) - Reticulocyte on 2 of 2 Sysmex XN analyzers 2. The laboratory failed to provide documentation for the following 1 of 4 comparison studies performed from 7/12/2023 to 7/24/2025: - Manual and automated urinalysis (due second half of 2024). 3. TS # 3 confirmed the findings above on 7/24/2025 at 1:00 pm.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature log records and interview with technical supervisor (TS) #3, the laboratory failed to document all corrective actions taken when room temperatures exceeded the laboratory's acceptable range for 4 of 31 days in May 2025 . Findings include: 1. On the day of the survey, 07/24/2025 at 04:20 pm, review of the the Penn Highlands Clearfield Room Temperature Check log revealed the following temperatures exceeded the laboratories acceptable range (20-25 degrees Celsius) for 4 of 31 days in May 2025: Location: Hallway Client Table Room Temperature - 05/02/2025: 26.0 degrees Celsius - 05/12/2025: 26.0 degrees Celsius - 05/14/2025: 26.0 degrees Celsius - 05/27/2025: 25.5 degrees Celsius 2. Further review of the temperature logs, revealed the Room Temp Check log instructions stated, "1. Record the current temperature. 2. Confirm that the temperature is within acceptable range. 3. If the temperature is not within this range, close the door and wait 5 minutes. If the temperature remains out of range, maintenance must be notified." 3. The laboratory failed to provide documentation of the corrective actions taken for temperature readings that exceeded the laboratory's acceptable range in May 2025. 4. TS #3 confirmed the finding above on 07/23/2025 at 04:30 pm.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's Microbiology Quality Control (QC) logs, maintenance records, and interview with Technical Supervisor (TS) #3 (CMS 209 form), the TS failed to perform and document the review of QC logs for 11 out of 52 weekly Microscan Walkaway Sensitivity QC reports for 2024 and Daily QC of Bactec Blood Culture Analyzer for 15 of 742 days from 07/12/2023 to 07/24/2024. Findings include: 1. On the day of survey, 07/24/2025, a review of the laboratory's Microbiology QC log, revealed the TS failed to provide documentation for the review of 11 out of 52 Microscan Walkaway Weekly Sensitivity QC reports performed for 2024. 2. Further onsite review of the laboratory's maintenance records revealed the TS

	failed to review Daily QC of Bactec Blood Culture Analyzer for 15 of 742 days from 07/12/2023 to 07/24/2024. 3. TS #3 confirmed the above findings on 07/24/2024 at 11: 45 pm.
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 review of the Laboratory Information System (LIS) policy, lack of documentation, and interview with Technical Supervisor (TS) #3, the laboratory failed to establish and follow a written policy for an ongoing mechanism to periodically monitor and verify the accuracy of calculations performed using 1 of 1 LIS (Cerner) from 7/12/2023 to 6/30/2025. Findings include: 1. On the date of the survey, 7/23 /2025 at 2:15 pm, review of the laboratory's LIS policies revealed the laboratory failed to indicate in the policy the ongoing mechanism in which the laboratory will periodically monitor and verify the accuracy of calculated results performed using 1 of 1 LIS (Cerner) from 7/12/2023 to 6/30/2024. 2. The laboratory failed to provide documentation for the periodic verification of the accuracy of the calculated data for 1 of 1 LIS (Cerner) used from 7/12/2023 to 6/30/2024. 3. TS #3 confirmed the findings above on 7/23/2024 at 2:30 pm.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review, lack of documentation, and interview with Technical Consultant (TC) #7, the TC failed to evaluate the test performance of 9 of 26 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for blood gas examinations (Chemistry) performed from 7/12/2023 to 7/24 /2025. Findings Include: 1. Review of the laboratory's 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. During interview, 7/24/2025 at 09:30 am, when asked by the examiner how testing personnel (TP) were assessed for procedure #5 of the laboratory's competency policy, TC #7 stated, "point #5 was assessed using proficiency testing samples and results". 3. Review onsite of proficiency testing (PT) attestation records for blood gas analyses revealed TP # 17 and # 20 (CMS 209,dated

	07/03/2025) performed all PT samples for the events in 2024 and 2025. 4. The laboratory could not provide documentation for the evaluation of test performance through internal blind testing or external proficiency testing (PT) samples for blood gas examinations (Chemistry) for the 9 of 26 TP that did not perform PT testing from (CMS 209, TP # 16, #18, #19, #21, #22, #23, #24, #25, and #26) from 7/12/2023 to 7 /24/2025. 5. TC #7 confirmed the findings above on 7/24/2025 at 9:30 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 interviews with Technical Supervisor (TS) #2, the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established, maintained and documented to assure the quality of services provided by the laboratory for 2 of 2 years from 07/12/2023 to the date of survey. Findings include: 1. On the date of the survey, 07/24/2025 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 2 of 2 years from 7/12/2023 to 07/24/2025. 2. TS #2 confirmed the findings above on 07/24/2025 at 11:30 am.
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 3 of 3 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 7/12/2023 to 7/24/2025. Findings include: 1. On the day of survey, 7/24/2025 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 issue 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 the non-pathologist gross examinations was

	completed within 24 hours as outlined by policy for 3 of 3 patient test reports reviewed from 07/12/2023 to 07/24/2025. 3. TS #3 confirmed the findings above on 7 /24/2025 at 11:30 am.
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 2 of 26 testing personnel (TP) for monitoring the recording and reporting of test results of macroscopic histopathology examinations performed in 2024 and 2025. Findings Include: 1. On the day of survey, 7/24/2025, 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 2 of 26 TP (CMS 209 TP #12 and #13, dated 07/03/2025) for macroscopic histopathology (grossing and inking) performed from 7/12/2023 to 7/24 /2025. 3. TS #3 confirmed the findings above on 7/24/2025 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 the Technical Supervisor (TS) #3, the TS failed to to assess the competency of 2 of 26 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 7 /12/2023 to 7/24/2025. Findings Include: 1. On the day of survey, 7/24/2025, 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 2 of 26 TP (CMS 209, TP #12 and #13) that performed macroscopic histopathology (grossing and inking) examinations from 7/12/2023 to 7 /24/2025. 3. TS #3 confirmed the findings above on 7/24/2025 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 the Technical Supervisor (TS) #3, the TS failed to to assess the competency of 2 of 26 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 7/12/2023 to 7/24/2025. Findings Include: 1. On the day of survey, 7 /24/2025, 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 2 of 26 TP (CMS 209, TP #12 and #13) that performed macroscopic histopathology (grossing and inking) examinations from 7/12/2023 to 7/24/2025. 3.TS #3 confirmed the findings above on 7/24/2025 at 12:30 pm.