Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2275839	10/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cls Labs, Llc	1350 W Walnut Ln Ste 120, Irving, TX	

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	An unannounced onsite complaint survey was performed on October 23rd, 2025, and the laboratory was found to NOT be in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) 493.1447 Technical Supervisor The complaint was substantiated. The laboratory's failure to be in compliance with the CLIA regulations was found to pose immediate jeopardy to the patients served by the laboratory.
D3007	FACILITIES CFR(s): 493.1101(b) (b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to supply appropriate and sufficient equipment for patient analysis for one of one specialty (microbiology) in October 2025. Findings included: 1. During a tour of the laboratory on 10/23/2025 at 03:25 PM, the surveyor observed two pipettes in the Post-PCR sample processing area. Further observations revealed the laboratory did not possess the correct pipette tips for the observed pipettes. 2. Review of laboratory policy, "Pipette Policy" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...Purpose: This procedure is to classify and describe the use of pipettes/pipettors used for clinical laboratory assays. Standard practice at this laboratory is to use pipettes for the reconstitution of reagents, standards, and controls, to use automatic pipettors for specimen dilutions and pretreatments ..." 3. In an interview on 10/23/2025 at 03:29 PM in the laboratory Post-PCR room, testing person one (TP-1) stated the observed pipettes were not in use. TP-1 further stated the in-use pipettes were sent to another laboratory location and were not currently available for testing. This confirmed the laboratory failed to supply

	appropriate and sufficient equipment for patient analysis for one of one specialty (microbiology) in October 2025. Word Key PCR- Polymerase Chain Reaction
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 Centers for Medicare and Medicaid Services (CMS)-209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have a policy in place for technical supervisor competency evaluation for 20 of 20 months in 2024 and 2025 (01/2024-09/2025). Findings included: 1. Review of CMS-209 form during the survey process on 10/23/2025, revealed one laboratory personnel documented as performing technical supervisor (TS-1) responsibilities. 2. Review of laboratory policy manual revealed the laboratory failed to have a policy in place for technical supervisor competency evaluations. The surveyor requested a specific policy pertaining to technical supervisor competency evaluations, and none was provided. 3. Review of personnel records revealed no documentation of competency evaluations for TS-1 in 2024 and 2025. 4. In an interview on 10/23/2025 at 12:15 PM, in the facility office area, testing person one (TP-1) was asked to provide documentation of competency for TS-1 in 2024 and 2025. TP-1 stated all documentation available was provided. This confirmed the laboratory failed to have a policy in place for technical supervisor competency evaluation for 20 of 20 months in 2024 and 2025 (01/2024-09 /2025).
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 laboratory American Proficiency Institute (API) Proficiency Testing (PT) records in 2025, laboratory policy, and confirmed in interview, the laboratory failed to have documentation of verifying the accuracy of microbiology analytes not scored by the PT program for two of two events in 2025. Findings included: 1. Review of API PT records in 2025, revealed the following: "Proficiency Evaluation Proficiency Testing Microbiology 2025 ... ... 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." Further review revealed the following "Not Graded" analytes in 2025: API Microbiology 2025 1st Event a. Analyte: CTX-M Group 1 Samples: UTI-3 and UTI-4 Performance: Not Graded b. Analyte: Resistance Gene dfrA Samples: UTI-3 and UTI-4 Performance: Not Graded c. Analyte: Resistance Gene KPC Samples: UTI-3 and UTI-4 Performance: Not Graded d. Analyte: Resistance Gene mecA Samples: UTI-1, UTI-2, UTI-3, UTI-4 and UTI-5 Performance: Not Graded e. Analyte: Resistance Gene NDM Samples: UTI-3 and UTI-4 Performance:

	Not Graded f. Analyte: Resistance Gene qnr Samples: UTI-3 and UTI-4 Performance: Not Graded g. Analyte: Resistance Gene sul Samples: UTI-3 and UTI-4 Performance: Not Graded h. Analyte: Resistance Gene vanA/B Samples: UTI-1,UTI-2 and UTI-4 Performance: Not Graded API Microbiology 2025 2nd Event i. Analyte: CTX-M Group 1 Samples: UTI-1, UTI-3 and UTI-4 Performance: Not Graded j. Analyte: Resistance Gene dfrA Samples: UTI-1 Performance: Not Graded k. Analyte: Resistance Gene KPC Samples: UTI-1 and UTI-4 Performance: Not Graded l. Analyte: Resistance Gene mecA Samples: UTI-1, UTI-2, UTI-3, and UTI-5 Performance: Not Graded m. Analyte: Resistance Gene NDM Samples: UTI-1 and UTI-4 Performance: Not Graded n. Analyte: Resistance Gene qnr Samples: UTI-1 and UTI-4 Performance: Not Graded o. Analyte: Resistance Gene sul Samples: UTI-1 and UTI-4 Performance: Not Graded p. Analyte: Resistance Gene vanA/B Samples: UTI-1,UTI-2, UTI-3 and UTI-5 Performance: Not Graded 2. Review of laboratory policy, "Proficiency Testing Plan" (Approved by the laboratory director on 08/08/2023) revealed the following: " ...Ungraded PT: Ungraded PT Surveys require internal assessment of performance, documented evaluation and approval by the LD ... An ungraded PT challenge will be handled as a failed survey and require internal analysis against survey results utilizing CLIA limits." The surveyor requested the above documentation for the ungraded PT events in 2025, and none were provided. 3. In an interview on 10/23/2025 at 12:22 PM, in the facility office area, testing person one (TP-1) was asked to provide documentation of verifying analytes not graded by the PT agency in 2025. TP-1 stated verifications were not completed for any ungraded analytes. This confirmed the laboratory failed to have documentation of verifying the accuracy of microbiology analytes not scored by the PT program for two of two events in 2025. Word Key LD- Laboratory Director
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient requisitions, patient final reports, and confirmed in interview, the laboratory failed to document a written or electronic request for patient testing for one of seven patients randomly reviewed in April 2025. Findings included: 1. Review of laboratory policy, "Laboratory Quality Assurance Program-Quality Assessment" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...B. PRE-ANALYTIC PHASE- see CLIA rules and guidelines for details of requirements of these indicators i. Test tracking (requisitions) - to assure compliance and reduce medical errors ii. Specimen handling, collection and labeling- to assure quality testing and reduce medical errors iii. Specimen stability- to assure quality testing" 2. Review of patient final reports in April 2025, revealed the following one of seven patients randomly reviewed, that did not have documentation of a written or electronic test request prior to patient testing: Patient 1: See Patient Alias List Testing performed: UTI and STI PCR panels The surveyor requested the above documentation, and none was provided. 4. In an interview on 10 /23/2025 at 03:40 PM, in the laboratory office area, testing person one (TP-1), was asked to provide the above documentation, and none was provided. This confirmed the laboratory failed to document a written or electronic request for patient testing for one of seven patients randomly reviewed in April 2025. Word Key UTI- Urinary Tract Infection STI- Secually Transmited Infection PCR- Polymerase Chain Reaction

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 surveyor observation, review of laboratory documentation and confirmed in interview, the laboratory failed to meet the requirements of the analytic systems for one of one specialty (microbiology) from 2024-2025 (October 2024-October 2025), as evidenced by: 1. The laboratory failed to include a panic or alert value policy for one of one Sexually Transmitted Infection (STI) PCR microbiology method in 2025. Refer to D5403. 2. The laboratory failed to document reagent information on one of one conical tube found in 2025. Refer to D5415 I. 3. The laboratory failed to document reagent expiration dates for one of one prepared reagent bottle found in 2025. Refer to D5415 II. 4. The laboratory failed to remove microbiology reagents from use prior to their expiration date for four of seven reagents observed in 2025. Refer to D5417. 5. The laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 I. 6. The laboratory failed to perform analytic sensitivity to include interfering substances for 10 of 10 STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 II. 7. The laboratory failed to document operator variance in precision, in two of two method establishment studies in 2024. Refer to D5423 III. 8. The laboratory failed to verify test performance specifications for two of two established methods after laboratory relocation in November 2024. Refer to D5423 IV. 9. The laboratory failed to document weekly hood maintenance for three of three weeks in October 2025. Refer to D5433 I. 10. The laboratory failed to document centrifuge weekly maintenance for three of three weeks in October 2025. Refer to D5433 II. 11. The laboratory failed to document yearly centrifuge maintenance and function checks for one of one year in 2024. Refer to D5435. 12. The laboratory failed to document corrective actions when freezer temperatures fell outside acceptable range for 11 of 21 operating days in 2025 (09/16-10/22/2025). Refer to D5781.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria

	for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, patient final reports, and confirmed in interview, the laboratory failed to include a panic or alert value policy for one of one Sexually Transmitted Infection (STI) PCR microbiology method in 2025. Findings Included: 1. Review of laboratory procedure manual on 10/23/2025, revealed the laboratory failed to document a panic or alert policy for STI PCR patient results. 2. Review of patient reports in April 2025, revealed a minor with positive STI PCR analytes documented. The following resulted as positive in the patient chart: Patient 1: See Patient Alias Chart Positive STI analytes: a. Chlamydia trachomatis b. Neisseria gonorrhoeae c. Trichomonas vaginalis 3. In a phone interview on 10/23/205 around 2: 40PM with the laboratory director (LD), the LD was asked to provide a panic or alert policy for the STI PCR analytes. The LD stated there were "no panic or alert values" in qualitative testing. The LD was asked if the above referenced patient results would be considered a panic or alert value. The LD confirmed these positive results would be considered a panic or alert value for the patient. This confirmed the laboratory failed to include a panic or alert value policy for one of one Sexually Transmitted Infection (STI) PCR method in 2025. Word Key PCR- Polymerase Chain Reaction
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: I. Based on surveyor observation, and confirmed in interview, the laboratory failed to document reagent information on one of one conical tube observed in 2025. Findings included: 1. During a tour of the facility on 10/23/2025 at 01:54 PM in the facility Post PCR Room, the surveyor observed one unlabeled conical tube, placed in a plastic bag containing Youseq PCR quality controls, located on a shelf inside "Freezer #1". No documentation of the following reagent storage requirements were documented on the conical tube: a. Identity b. Storage Requirements c. Preparation and expiration dates d. Other pertinent information required for proper use The surveyor inquired as to the contents of the unlabeled tube. Testing person one (TP-1) stated the conical tube contained PCR Master Mix reagent solution used in patient testing. 2. In an interview on 10/23/2025 at 01:55 PM, in the Post PCR Room, TP-1 confirmed the laboratory failed to document reagent information on one of one conical tube observed in 2025. II. Based on surveyor observation, and confirmed in interview, the laboratory failed to document reagent expiration dates for one of one prepared reagent bottle observed in 2025. Findings included: 1. During a tour of the facility on 10/23

	/2025 at 01:58 PM, in the laboratory Pre-PCR Room, the surveyor observed one 70% Ethanol reagent bottle prepared on 06/29/2022. The expiration date was not documented on the bottle. 2. In an interview on 10/23/2025 at 02:04 PM, in the Pre-PCR Room, TP-1 confirmed the laboratory failed to document reagent expiration dates for one of one prepared reagent bottle observed in 2025. Word Key PCR-Polymerase Chain Reaction
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 review of Centers for Medicare and Medicaid (CMS)-116 form, surveyor observation, and confirmed in interview, the laboratory failed to remove microbiology reagents from use prior to their expiration date for four of seven reagents observed in 2025. Findings included: 1. Review of CMS-116 form submitted at time of survey, 10 /23/2025, revealed the laboratory processed 500 microbiology patient tests annually since testing began in October 2024. 2. During a tour of the facility on 10/23/2025 at 01:58 PM in the Pre-PCR Room, the surveyor observed the following expired reagents stored in the wall cabinet, available for patient sample processing: a. Reagent: Applied Biosystems Mag/Max Viral/Pathogen Elution Buffer Lot Number: 01208667 Expiration Date: 12-27-2022 b. Reagent: Applied Biosystems Mag/Max Viral/Pathogen Nucleic Acid Isolation Lot Number: 01167676 Expiration Date: 09-30-2022 (Note: This reagent bottle was discolored and contained dried reagent on the inside of the bottle.) c. Reagent: Applied Biosystems Mag/Max Viral/Pathogen Wash Solution Lot Number: 01210878 Expiration Date: 01-04-2023 d. Reagent: Applied Biosystems Ultra Pure Distilled Water DNAse, RNAse, Free Lot Number: 2360334 Expiration Date: 02-28-2024 (Note: This reagent is used as a negative quality control in all patients tested.) 3. In an interview on 10/23/2025 at 02:04 PM, in the Pre-PCR Room, testing person one (TP-1) was asked if the expired reagents had been used for patient testing. TP-1 stated, "Yeah. They've been on me about those." TP-1 further stated these were the only reagents available for patient testing in the facility. This confirmed the laboratory failed to remove microbiology reagents from use prior to their expiration date for four of seven reagents observed in 2025.
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:
I. Based on surveyor observation, review of laboratory policy, laboratory Urinary Tract Infection (UTI) establishment documentation, patient final reports and confirmed in interview, the laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Findings included: 1. During a tour of the facility on 10/23/2024, the surveyor observed one CFx Opus 384 PCR analyzer (Serial Number: 670123) available for patient UTI analysis. 2. Review of laboratory policy, "SOP-QMS-01 Method validation and verification record" (Approved by the laboratory director on 08/02/2024) revealed the following list of requirements for method establishment of laboratory developed tests (LDT): "Validation of LDT Stability Linearity Accuracy and precision Matrix effect Analytical Specificity Carryover Interference Method comparison" 3. Review of laboratory UTI method establishment documentation (Approved by the laboratory director on 10/15/2024) revealed the laboratory failed to document accuracy and analytic specificity to include interfering substances for the following 32 analytes: a. Acinetobacter baumannii b. Citrobacter freundii c. Citrobacter koseri d. Enterobacter cloacae e. Enterococcus faecalis f. Enterococcus faecium g. Escherichia coli h. Klebsiella aerogenes i. Klebsiella oxytoca j. Klebsiella pneumoniae k. Morganella morganii l. Proteus mirabilis m. Pseudomonas aeruginosa n. Serratia marcescens o. Staphylococcus aureus p. Staphylococcus epidermidis q. Staphylococcus saprophyticus r. Streptococcus agalactiae s. Streptococcus pyogenes t. Candida albicans u. Candida glabrata v. Candida krusei w. Candida parapsilosis x. Candida tropicalis y. Resistance Gene: CTX-M Group 1 z. Resistance Gene: dfrA aa. Resistance Gene: KPC bb. Resistance Gene:mecA cc. Resistance Gene: NDM dd. Resistance Gene: qnr ee. Resistance Gene: sul ff. Resistance Gene: vanA/B The surveyor requested the above missing establishment documentation, and none was provided. 4. Random review of UTI patient reports in 2025, revealed seven patients tested for the above UTI analytes in April 2025. (Note: Laboratory has not received any UTI patients from facility clients since 04/15/2025.) 5. During an interview on 10 /23/2025 at the 01:15 PM, testing person one (TP-1) stated all UTI establishment documentation available had been provided to the surveyor. This confirmed the laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). II. Based on surveyor observation, review of laboratory policy, laboratory Sexually Transmitted Infections (STI) establishment documentation, patient final reports and confirmed in interview, the laboratory failed to perform analytic sensitivity to include interfering substances for ten of ten STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Findings included: 1. During a tour of the facility on 10/23/2024, the surveyor observed one CFx Opus 384 PCR analyzer (Serial Number: 670123) available for patient STI analysis. 2. Review of laboratory policy, "SOP-QMS-01 Method validation and verification record" (Approved by the laboratory director on 08/02/2024) revealed the following list of requirements for method establishment of laboratory developed tests (LDT): "Validation of LDT Stability Linearity Accuracy and precision Matrix effect Analytical Specificity Carryover Interference Method comparison" 3. Review of laboratory UTI method establishment documentation (Approved by the laboratory director on 10/15/2024) revealed the laboratory failed to document analytic specificity to include interfering substances for the following ten analytes: a. Chlamydia trachomatis b. Gardnerella vaginalis c. Mycoplasma d. Mycoplasma hominis e. Neisseria gonorrhoeae f. Treponema pallidum g. Ureaplasma parvum h. Trichomonas vaginalis i. Herpes simplex virus type 1 j. Herpes simplex virus type 2 The surveyor

	requested the above missing validation documentation, and none was provided. 4. Random review of STI patient reports in 2025, revealed 10 patients tested for the above UTI analytes in April 2025. (Note: Laboratory had no documentation of any STI patients from facility clients since 04/15/2025.) 5. During an interview on 10/23 /2025 at the 01:15 PM, testing person one (TP-1) stated all STI establishment documentation available had been provided to the surveyor. This confirmed the laboratory failed to perform analytic sensitivity to include interfering substances for ten of ten analytes (STI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). III. Based on review of laboratory Urinary Tract Infection (UTI) and Sexually Transmitted Infection (STI) establishment documentation, Centers for Medicare and Medicaid (CMS)-209 form, and confirmed in interview, the laboratory failed to document operator variance in precision, in two of two method establishments in 2024. Findings included: 1. Review of laboratory UTI and STI establishment documentation (Approved by the laboratory director on 10/15/2024), revealed the laboratory failed to document complete precision studies to include operator variance. The technical supervisor (TS-1) was the only personnel documented as performing UTI and STI method validations in 2024. The surveyor requested the above documentation, and none was provided. 2. Review of the CMS-209 form submitted at the time of survey, 10/23/2025, revealed the technical supervisor (TS-1) was not listed as a testing person. 3. In an interview on 10/23/2025 at 12:14 PM, in the laboratory office area, testing person one (TP-1) stated only the technical supervisor (TS-1) performed the establishment procedures, and all establishment documentation available had been provided to the surveyor. This confirmed the laboratory failed to document operator variance in precision, in two of two method establishments in 2024. IV. Based on laboratory establishment documentation, and confirmed in interview, the laboratory failed to document test performance verification for two of two established methods after laboratory relocation in November 2024. Findings included: 1. Review of laboratory validation documentation, revealed the laboratory director approved method establishments of Urinary Tract Infection (UTI) and Sexually Transmitted Infection (STI) PCR panels on 10/15/2024. 2. In a phone interview on 10/23/2025 at 01:18 PM with the technical supervisor (TS-1), TS-1 stated the laboratory relocated to the current location "around November-December 2024". TS-1 was asked to provide establishment of test performance following laboratory relocation. TS-1 stated all establishment documentation following the relocation was no longer accessible. This confirmed the laboratory failed to document test performance verification for two of two established methods after laboratory relocation in November 2024. Word Key PCR- Polymerase Chain Reaction
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of laboratory policy, laboratory maintenance logs in 2025, and confirmed in interview, the laboratory failed to document weekly hood maintenance for three of three weeks in October 2025. Findings included: 1. During a tour of the facility on 10/23/2025, the surveyor observed one fume hood

	used for PCR patient sample processing. 2. Review of laboratory policy, "Maintenance & Safety Checks" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...the laboratory must establish a maintenance/function check protocol and perform and document activities." 3. Review of laboratory hood maintenance logs in October 2025, revealed the following weeks maintenance was not documented: October 2025 a. 10/01-10/03 b. 10/06-10/10 c. 10/13-10/17 The surveyor requested documentation of maintenance for the above weeks in October, and no documentation was provided. 4. In an interview on 10/23/2025 at 03:42 PM, in the laboratory office area, testing person one (TP-1) confirmed the laboratory failed to document weekly hood maintenance for three of three weeks in October 2025. Word Key PCR- Polymerase Chain Reaction II. Based on surveyor observation, review of laboratory policy, laboratory maintenance logs in 2025, and confirmed in interview, the laboratory failed to document centrifuge weekly maintenance for three of three weeks in October 2025. Findings included: 1. During a tour of the facility on 10/23 /2025, the survey observed one centrifuge (Serial Number: 5415C) used for PCR patient sample processing. 2. Review of laboratory policy, "Maintenance & Safety Checks" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...the laboratory must establish a maintenance/function check protocol and perform and document activities. The following equipment and analyzers will have maintenance and function checks performed and documented: ...3. Centrifuges" 3. Review of laboratory centrifuge maintenance logs in October 2025, revealed the following: "1. Weekly maintenance Wipe the centrifuge outside, inside and the rotor with 70% Ethanol. Update the log." Further review revealed the following weeks centrifuge maintenance was not documented: October 2025 d. 10/01-10/03 e. 10/06-10 /10 f. 10/13-10/17 The surveyor requested documentation of maintenance for the above weeks in October, and no documentation was provided. 4. In an interview on 10 /23/2025 at 03:42 PM, in the laboratory office area, testing person one (TP-1) confirmed the laboratory failed to document weekly centrifuge maintenance for three of three weeks in October 2025.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, laboratory maintenance logs in 2024, and confirmed in interview, the laboratory failed to document yearly centrifuge maintenance and function checks for one of one year in 2024. Findings included: 1. During a tour of the facility on 10/23/2025, the survey observed one centrifuge used for PCR patient sample processing. 2. Review of laboratory policy, "Maintenance & Safety Checks" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...the laboratory must establish a maintenance/function check protocol and perform and document activities. The following equipment and analyzers will have maintenance and function checks performed and documented: ...3. Centrifuges- Yearly maintenance and function checks outlined below: -The centrifuge, rotors, and cushions should be cleaned yearly, or when visibly soiled.

	Clean these items in warm water with mild detergent solution. Disinfect with a solution of 10% bleach. Dry thoroughly before placing back in use." 3. Review of laboratory centrifuge maintenance documentation in 2024, revealed the laboratory failed to document yearly maintenance in 2024. The surveyor requested documentation of the above yearly maintenance in 2024, and none was provided. 4. In an interview on 10/23/2025 at 03:42 PM, in the laboratory office area, testing person one (TP-1) confirmed the laboratory failed to document yearly centrifuge maintenance and function checks for one of one year in 2024.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS)-116 form, laboratory policy, quality control records, and confirmed in interview, the laboratory failed to monitor over time the accuracy and precision of test performance for two of two microbiology methods performed in 2025. Findings included: 1. Review of CMS-116 form submitted at time of survey the laboratory performed Sexually Transmitted Infection (STI) and Urinary Tract Infection (UTI) patient testing. 2. Review of laboratory policy. "SOP-QMS-01: Quality Management System for the Lab (Quality Manual)" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...9. Measures (proficiency and QC charts) ...Also, important quality indicator of the laboratory is the review of the control charts (Levey Jennings) on a daily, weekly or monthly basis." 3. Review of STI and UTI quality control (QC) records in 2025 (January-April), revealed the laboratory failed to monitor QC over time. The surveyor requested the above documentation and none was provided. 4. In a phone interview on 10/23/2025 at 02:59 PM, technical supervisor one (TS-1) confirmed the laboratory failed to monitor over time the accuracy and precision of test performance for two of two polymerase chain reaction (PCR) methods performed in 2025.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, review of environmental logs, corrective action logs, and confirmed in interview, the laboratory failed to document corrective actions when freezer temperatures fell outside acceptable range for 11 of 21 operating days in 2025 (09/16-10/22/2025). Findings included: 1. During a tour of the facility on 10/23/2025, the survey observed one freezer (Freezer #1) storing PCR reagents and patient samples. 2. Review of laboratory environmental logs in 2025 revealed the following freezer acceptable temperature range: -15 to -25 C Further review revealed the following days in September and October 2025, when documented temperatures fell outside the above acceptable temperature range: September 2025 a. Date temperature recorded: 09/16/2025 Temperature recorded: -28.0 C Difference from acceptable temperature: 3 C b. Date temperature recorded: 09/22/2025 Temperature recorded: -26.0 C Difference from acceptable temperature: 1 C c. Date temperature recorded: 09 /26/2025 Temperature recorded: -26.0 C Difference from acceptable temperature: 1 C d. Date temperature recorded: 09/29/2025 Temperature recorded: -26.0 C Difference from acceptable temperature: 1 C e. Date temperature recorded: 09/30/2025 Temperature recorded: -26.0 C Difference from acceptable temperature: 1 C October 2025 f. Date temperature recorded: 10/02/2025 Temperature recorded: -28.0 C Difference from acceptable temperature: 3 C g. Date temperature recorded: 10/03 /2025 Temperature recorded: -27.0 C Difference from acceptable temperature: 2 C h. Date temperature recorded: 10/07/2025 Temperature recorded: -14.0 C Difference from acceptable temperature: 1 C i. Date temperature recorded: 10/15/2025 Temperature recorded: -27.0 C Difference from acceptable temperature: 2 C j. Date temperature recorded: 10/21/2025 Temperature recorded: -27.0 C Difference from acceptable temperature: 2 C k. Date temperature recorded: 10/22/2025 Temperature recorded: -27.0 C Difference from acceptable temperature: 2 C 3. Review of laboratory corrective action logs in 2025, revealed no documentation of corrective actions for the above days freezer temperatures were documented outside the acceptable temperature range. The surveyor requested documentation for the above days in 2025, and no documentation was provided. 4. In an interview on 10/23/2025 at 2:59 PM, in the laboratory office area, testing person one (TP-1) confirmed the laboratory failed to document corrective actions when freezer temperatures fell outside acceptable range for 11 of 21 operating days in 2025 (09/16-10/22/2025). Word Key PCR- Polymerase Chain Reaction C- Celsius
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: Based on surveyor observation, review of laboratory documentation, and confirmed in interview, the laboratory failed to have a quality assessment plan which identified and corrected issues in analytic systems for one of one specialty (microbiology) in 2024 and 2025, as evidenced by: Findings included: 1. The laboratory failed to include a panic or alert value policy for one of one established Sexually Transmitted Infection (STI) PCR microbiology method in 2025. Refer to D5403. 2. The laboratory failed to

	document reagent information on one of one conical tube found in 2025. Refer to D5415 I. 3. The laboratory failed to document reagent expiration dates for one of one prepared reagent bottle found in 2025. Refer to D5415 II. 4. The laboratory failed to remove microbiology reagents from use prior to their expiration date for four of seven reagents observed in 2025. Refer to D5417. 5. The laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 I. 6. The laboratory failed to perform analytic sensitivity to include interfering substances for 10 of 10 STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 II. 7. The laboratory failed to document operator variance in precision, in two of two method establishments in 2024. Refer to D5423 III. 8. The laboratory failed to verify test performance specifications for two of two established methods after laboratory relocation in November 2024. Refer to D5423 IV. 9. The laboratory failed to document weekly hood maintenance for three of three weeks in October 2025. Refer to D5433 I. 10. The laboratory failed to document centrifuge weekly maintenance for three of three weeks in October 2025. Refer to D5433 II. 11. The laboratory failed to document yearly centrifuge maintenance and function checks for one of one year in 2024. Refer to D5435. 12. The laboratory failed to document corrective actions when freezer temperatures fell outside acceptable range for 11 of 21 operating days in 2025 (09/16-10/22/2025). Refer to D5781.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on Center for Medicaid and Medicare Services (CMS)-116 form, patient final reports and confirmed in interview, the laboratory failed to document the correct laboratory location on patient reports for seven of seven patients randomly reviewed in April 2025. Findings included: 1. Review of CMS-116 form submitted at time of survey, revealed the following laboratory physical address: 1350 W Walnut Hill Ln Suite 120 Irving, TX 75038 2. Review of patient final reports in April 2025, revealed seven of seven randomly reviewed final reports without the above physical address of test performance documented. (See Patient Alias List) 3. In an interview on 10/23 /2025 at 02:59 PM, in the laboratory office area, testing person one (TP-1) stated the laboratory relocated in 2024, and the previous location was not updated on patient final reports. This confirmed the laboratory failed to document the laboratory address location on patient reports for seven of seven patients randomly reviewed in April 2025. II. Based on staff interview, review of laboratory method validation, laboratory policy, patient final reports and confirmed in interview, the laboratory failed to notify the appropriate individual concerning unacceptable specimens for two of seven patients reviewed in 2025. Findings included: 1. During the survey entrance conference on 10/23/2025 at 11:29 AM, testing person one (TP-1) stated the

	laboratory only received shipped specimens from offsite facilities for patient testing. 2. Review of laboratory policy, "Laboratory Quality Assurance Program-Quality Assessment" (Approved by the laboratory director on 05/07/2024) revealed the following: " ...B. PRE-ANALYTIC PHASE- see CLIA rules and guidelines for details of requirements of these indicators i. Test tracking (requisitions)- to assure compliance and reduce medical errors ii. Specimen handling, collection and labeling- to assure quality testing and reduce medical errors iii. Specimen stability- to assure quality testing" 3. Review of laboratory Urinary Tract Infection (UTI) PCR establishment procedure (Approved by the laboratory director on 10/15/2024) revealed the following: " ...Stability: 5 days "Room Temperature: 15-25 C Refrigerator Temperature: 4-8 C" 4. Review of patient final reports in April 2025, revealed the following two of seven patients tested beyond the five day established specimen stability limits: a. Patient 2 (See Patient Alias List) Collection Date: 04/09 /2025 Received Date: 04/14/2025 Reported Date: 04/15/2025 Days beyond stability: 1 b. Patient 3 (See Patient Alias List) Collection Date: 04/09/2025 Received Date: 04/14 /2025 Reported Date: 04/15/2025 Days beyond stability: 1 5. In an interview on 10/23 /2025 at 03:39 PM, in the laboratory office area, after presentation of the above findings, testing person one (TP-1) confirmed the laboratory failed to notify the appropriate individual concerning unacceptable specimens for two of seven patients reviewed in 2025. Word Key C- Celsius
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 review of the laboratory's records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to provide overall management of the laboratory for one of one high complexity specialty (Microbiology) from October 2024- October 2025, as evidenced by: 1. The laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in high complexity testing, for one of one year from October 2024- October 2025. Refer to D6079. 2. The laboratory director failed to ensure laboratory establishment studies were adequate. Refer to D6086. 3. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality, for one of one high complexity specialty (Microbiology) from October 2024- October 2025. Refer to D6093. 4. The laboratory director failed to ensure that one of one testing person (TP-1) received the appropriate training in high complexity testing prior to patient testing. Refer to D6102. 5. The laboratory director failed to document policy approval for 1 of 12 policies reviewed in 2025. Refer to D6106.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently,

	and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient final reports, and confirmed in interview, the laboratory director failed to ensure the overall operation of the laboratory and compliance with applicable regulations for one of one year, from October 2024-October 2025, as evidenced by: 1. The laboratory director failed to ensure laboratory establishment studies were adequate prior to patient testing. Refer to D6086. 2. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality, for one of one high complexity specialty (Microbiology) from October 2024- October 2025. Refer to D6093. 3. The laboratory director failed to ensure that one of one testing person (TP-1) received the appropriate training in high complexity testing prior to patient testing. Refer to D6102. 4. The laboratory director failed to document policy approval for 1 of 12 policies reviewed in 2025. Refer to 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 surveyor observation, review of laboratory documentation, patient final reports, and confirmed in interview, the laboratory director failed to ensure laboratory establishment studies were adequate prior to patient testing for two of two methods validated in 2024, as evidenced by: 1. The laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 I. 2. The laboratory failed to perform analytic sensitivity to include interfering substances for 10 of 10 STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 II. 3. The laboratory failed to document operator variance in precision, in two of two method establishments in 2024. Refer to D5423 III. 4. The laboratory failed to verify test performance specifications for two of two established methods after laboratory relocation in November 2024. Refer to D5423 IV.
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 surveyor observation, review of laboratory documentation, and confirmed in interview, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality, for one of one high complexity specialty (Microbiology) from October 2024- October 2025, as evidenced by: 1. The laboratory failed to have a quality assessment plan which identified and corrected issues in analytic systems for one of one specialty (Microbiology) performed from 2024-2025. Refer to D5791.
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 laboratory policy, and confirmed in interview, the laboratory director failed to document policy approval for 1 of 12 policies reviewed in 2025. Findings included: 1. Review of laboratory policy, "SOP-GEN-10 Title: Pathogen Reporting and PCR QC tracking through LJ charts" (Effective date: 10/06/2025) revealed the laboratory director failed to document approval of the laboratory policy. 2. In an interview on 10 /23/2025 at 03:49 PM, in the laboratory office area, testing person one (TP-1) confirmed the laboratory director failed to document policy approval for 1 of 12 policies reviewed in 2025.
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 review of the laboratory policy, establishment studies, patient final reports, and confirmed in interview, the technical supervisor failed to provide technical and scientific oversight as evidenced by: 1. The technical supervisor failed to provide technical and scientific oversight. Refer to D6112. 2. The technical supervisor failed to ensure establishment studies were complete prior to performing patient testing. Refer to D6115. 3. The technical supervisor failed to document one of one testing person's training in Microbiology in 2025. Refer to D6120.
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 laboratory policy, establishment studies, quality control records, patient final reports, and confirmed in interview, the technical supervisor failed to provide technical and scientific oversight as evidenced by: 1. The laboratory failed to document reagent information on one of one conical tube found in 2025. Refer to D5415 I. 2. The laboratory failed to document reagent expiration dates for one of one prepared reagent bottle found in 2025. Refer to D5415 II. 3. The laboratory failed to remove microbiology reagents from use prior to their expiration date for four of seven reagents observed in 2025. Refer to D5417. 4. The laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 I. 5. The laboratory failed to perform analytic sensitivity to include interfering substances for 10 of 10 STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 II. 6. The laboratory failed to document operator variance in precision, in two of two method establishments in 2024. Refer to D5423 III. 7. The laboratory failed to verify test performance specifications for two of two established methods after laboratory relocation in November 2024. Refer to D5423 IV. 8. The laboratory failed to document weekly hood maintenance for three of three weeks in October 2025. Refer to D5433 I. 9. The laboratory failed to document centrifuge weekly maintenance for three of three weeks in October 2025. Refer to D5433 II. 10. The laboratory failed to document yearly centrifuge maintenance and function checks for one of one year in 2024. Refer to D5435. 11. The laboratory failed to document corrective actions when freezer temperatures fell outside acceptable range for 11 of 21 operating days in 2025 (09/16-10/22/2025). Refer to D5781.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: The technical supervisor failed to ensure establishment studies were complete prior to performing patient testing for two of two Microbiology methods validated in 2024 as evidenced by: 1. The laboratory failed to perform accuracy and analytic sensitivity to include interfering substances for 32 of 32 UTI analytes (UTI Panel) performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 I. 2. The laboratory failed to perform analytic sensitivity to include interfering substances for 10 of 10 STI analytes performed in 2024 and 2025 (October 2024-October 23rd, 2025). Refer to D5423 II. 3. The laboratory failed to document operator variance in precision, in two of two method establishments in 2024. Refer to D5423 III. 4. The laboratory failed to verify test performance specifications for two of two established methods after laboratory relocation in November 2024. Refer to D5423 IV.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of

	all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS)-209 form, facility tour, personnel documentation, and confirmed in interview, the technical supervisor failed to document one of one testing person's training in Microbiology in 2025. 1. Review of the CMS-209 form submitted at time of survey, 10/23/2025. Revealed one testing person (TP-1) performing high complexity microbiology PCR testing. 2. During a tour of the facility on 10/23/2024, the surveyor observed one CFx Opus 384 PCR analyzer (Serial Number: 670123) available for patient analysis. 3. Review of TP-1 personnel documentation revealed a start date of 06/02/2025. Further review revealed no documented training for the CFx Opus 384 PCR analyzer. 4. In an interview on 10/23/2025, in the laboratory office area, the surveyor requested the above documentation of training from TP-1. TP-1 stated all documentation had been provided to the surveyor. This confirmed the technical supervisor failed to document one of one testing person's training in Microbiology in 2025.