Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464721	08/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Freedman Clinic Laboratory	176 Versailles Blvd, Alexandria, LA	

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 Validation survey was performed at Freedman Clinic of Internal Medicine, CLIA ID #19D0464721 on August 6, 2025. Freedman Clinic of Internal Medicine was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250: CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
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 the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a policy for competency assessment of the Technical Consultant to include, but not limited to, frequency of performance. 2. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Consultant. 3. In interview on August 6, 2025 at 10:58 a.m., the Technical Consultant confirmed the laboratory did not have a policy for competency assessment of the Technical Consultant.
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 laboratory's policies and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to perform assessment activities for unacceptable PT results for two (2) of ten (10) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Policy" revealed "All unacceptable PT results will be investigated, consultation will be obtained where indicated and remedial education will be performed, as appropriate...Any results given a passing score of less than 100% will be evaluated." 2. Review of the laboratory's American Proficiency Institute (API) PT records revealed the laboratory did not assess unacceptable results for the following events: a) 2024 Chemistry - Core - 1st Event: * Bilirubin, Direct - Sample CH-02 Unacceptable * Phosphorous - Sample CH-05 Unacceptable b) 2024 Chemistry - Core - 2nd Event * Cholesterol, HDL - Sample CH-07 Unacceptable 3. In interview on August 6, 2025 at 11:17 a.m., Testing Personnel 1 confirmed the laboratory did not assess the unacceptable results identified above.
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 by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for blood collection supplies stored in one (1) of one (1) rooms in the laboratory. Refer to D5413. 2. The laboratory failed to document the open expiration date for Hematology and Chemistry quality control materials. Refer to D5415. 3. The laboratory failed to ensure microbiology specimen collection supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Refer to D5417. 4. The laboratory failed to verify complete performance specifications for microalbumin and urine creatinine testing on the DCA Vantage analyzer. Refer to D5421. 5. The laboratory failed to perform maintenance on the DCA Vantage analyzer as required by the manufacturer for twelve (12) of twelve (12) months reviewed. Refer to D5429. 6. The laboratory failed to establish their own means and ranges for QC material utilized for erythrocyte sedimentation rate (ESR) testing. Refer to D5469. 7. The laboratory failed to follow their corrective action policy for quality control when chemistry quality control was outside of acceptable limits for one (1) of one (1) days reviewed. Refer to D5779. 8. The laboratory failed to establish complete procedures to identify issues within the analytic system. Refer to D5791.
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 observation, review of the manufacturer's instructions and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for blood collection supplies stored in one (1) of one (1) rooms in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the laboratory stored supplies in the laboratory to include, but not limited to, the following: a) BD Vacutainer SST Blood Collection Tubes (gold top) - Manufacturer's storage requirements: 4 - 25 degrees Celsius. b) BD Vacutainer K2E 7.2 mg Blood Collection Tubes - Manufacturer's storage requirements: 4 - 25 degrees Celsius. c) BD Vacutainer SST Blood Collection Tubes (red tiger top) - Manufacturer's storage requirements: 4 - 25 degrees Celsius. 2. Review of the laboratory's temperature log "Freedman Clinic Lab Laboratory Temperature & Humidity" revealed the laboratory defined the acceptable room temperature range as "64 degrees Fahrenheit - 87 degrees Fahrenheit" (17.8 - 30.6 degrees Celsius) which exceeded the manufacturer's upper limit. 3. In interview on August 6, 2025 at 2 p.m., Testing Personnel 1 confirmed the laboratory's acceptable upper limit for room temperature exceeded the manufacturer's upper limit as identified above.
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 observation, review of manufacturers' package inserts, and interview with personnel, the laboratory failed to document the open expiration date for Hematology and Chemistry quality control materials. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the following quality control materials in use for testing: a) Sysmex XN analyzer: *L1 XN-L Check: Lot 51511401, Manufacturer's expiration date 9/9/2025 *L2 XN-L Check: Lot 51511402, Manufacturer's expiration date 9/9/2025 *L3 XN-L Check: Lot 51511403, Manufacturer's expiration date 9/9/2025 b) Excyte ESR analyzer: *ESR Chex 1: Lot 50341380, Manufacturer's expiration date 2/3/2026 *ESR Chex 2: Lot 50341381, Manufacturer's expiration date 2/3/2026 c) Ortho Vitros 5600: * Vitros Performance Verifier I: Lot Y2110, Manufacturer's expiration 3/25/2026 * Vitros Performance Verifier II: Lot F2830, Manufacturer's expiration date 2/3/2027 2. Review of the manufacturers' package inserts and/or assay sheets for the quality control materials

	identified above revealed the following: a) "XN-L Check" package insert revealed "Opened vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." b) "ESR-Chex" assay sheet revealed "Open-vial stability 95 days." c) "Vitros Performance Verifier I" and "Vitros Performance Verifier II" assay sheet revealed: *"Reconstituted stability when stored at 2 - 8 degrees C" - "Stable for 7 days." - "Stable for 3 days: ALKP, ALKP (XT), ALT2, ALT2 (XT), ALTJ, ASTJ (XT), BuBc, Ca, Ca (XT), CK, TBIL, TBIL (XT)." 3. Further observation of the above identified quality control materials revealed the laboratory did not label the vials with open expiration dates. 4. In interview on August 6, 2025 at 4:30 p.m., Testing Personnel 1 confirmed the laboratory did not document the open expiration dates on the quality control vials identified above.
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 and interview with personnel, the laboratory failed to ensure microbiology specimen collection supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the following expired items: a) Copan eSwab - Lot: LN40072500, Expiration date: 6/13/2025, Quantity: One (1) swab b) Copan Transystem - L231514100, Expiration date: 2/14 /2025, Quantity: Nine (9) swabs c) BBL Cultureswab Plus collection and transport system for aerobes and anaerobes - Lot: L231292000, Expiration date: 5/14/2025, Quantity: Eight (8) swabs d) Copan eSwab - Lot: LN30422501, Expiration date: 11/30 /2025, Quantity: Eight (8) swabs 2. In interview on August 6, 2025 at 9:14 a.m., Testing Personnel 1 confirmed the items identified above were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to verify complete performance specifications for microalbumin and urine creatinine testing on the DCA Vantage analyzer. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the laboratory's policy

	"Analytic Processes" section "Verification of Performance Specifications" revealed "Our laboratory seeks support from the test system manufacturer to provide guidance in procedures to verify accuracy, precision, reportable range and reference range, as well as samples to conduct this testing." 3. Review of the performance specification studies for the DCA Vantage revealed the Laboratory Director approved the studies on August 5, 2025; however, the laboratory did not include the following: a) Reference range b) Precision to include day-to-day, run-to-run, within run, and operator variance c) Accuracy d) Laboratory Information System (LIS) verification 4. In interview on August 6, 2025 at 4:53 p.m., the Technical Consultant confirmed the laboratory did not perform the performance specification studies identified above.
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 observation; review of the manufacturer's operator's manual, the laboratory's performance specification records, and the laboratory's maintenance records; as well as interview with personnel, the laboratory failed to perform maintenance on the DCA Vantage analyzer as required by the manufacturer for twelve (12) of twelve (12) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the "DCA Vantage Analyzer Operator's Guide" section "Maintenance" revealed the following: a) "Weekly" * "Cleaning the Onboard Barcode Reader Window" * "Cleaning the Exterior" b) "Quarterly" * "Changing the Air Filter" * "Optical Test" 3. Review of the laboratory's performance specification records revealed the analyzer was approved by the Laboratory Director for testing August 5, 2025. 4. Review of the laboratory's maintenance records from August 2025 through July 2025 revealed the laboratory did not document weekly and/or quarterly maintenance on the DCA Vantage. 5. In interview on August 6, 2025 at 3:02 p.m., Testing Personnel 1 stated maintenance was performed on the DCA Vantage analyzer but was not documented.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on observation; review of manufacturer's package insert, the laboratory's quality control (QC) records, and the laboratory's test menu; and interview with

	personnel, the laboratory failed to establish their own means and ranges for QC material utilized for erythrocyte sedimentation rate (ESR) testing. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the laboratory performed ESR testing utilizing Streck ESR-Chex QC on the Excyte analyzer. 2. Review of the "Streck ESR-Chex" package insert detailed that each "individual laboratory establish its own means and limits." 3. Review of the laboratory's QC records revealed the laboratory did not have documentation of establishing their own QC means and ranges for Streck ESR Chex Lot L1 - 43441380 and L2 - 43441381. 4. In interview on August 6, 2025 at 1:43 p.m., Testing Personnel 1 stated the laboratory utilized the manufacturer's QC ranges. She confirmed the laboratory did not establish their own QC means and ranges for ESR testing. 5. Review of the laboratory's test menu revealed the laboratory performs 1,127 ESR tests annually.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies and quality control (QC) records, and interview with personnel, the laboratory failed to follow their corrective action policy for quality control when chemistry quality control was outside of acceptable limits for one (1) of one (1) days reviewed. Findings: 1. Observation by surveyor on August 6, 2025 at 8:40 a.m. revealed the laboratory utilized an Ortho Vitros 5600 analyzer for routine chemistry testing. 2. Review of the laboratory's policy "Analytic Processes" section "Quality Control" revealed "Quality control logs are maintained. The log includes the date tested, initials of the individual performed, the result obtained, an indication of whether the result was acceptable or not, and if not acceptable - corrective actions taken." 3. Review of chemistry quality control records from June 2025 revealed Chloride (Cl) QC was outside of the laboratory's established acceptable limits on June 11, 2025 and retested, but the laboratory did not document the corrective actions taken: *July 11, 2025: PV1 Chloride QC tested three (3) times. 4. In interview on August 6, 2025 at 2:15 p.m., Testing Personnel 1 stated the laboratory did not have a log for documenting corrective actions taken when QC is outside of the acceptable limits. She confirmed the laboratory did not document corrective actions for Chloride as identified above.
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 observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory

	had a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for blood collection supplies stored in one (1) of one (1) rooms in the laboratory. Refer to D5413. b) The laboratory failed to document the open expiration date for Hematology and Chemistry quality control materials. Refer to D5415. c) The laboratory failed to ensure microbiology specimen collection supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Refer to D5417. d) The laboratory failed to verify complete performance specifications for microalbumin and urine creatinine testing on the DCA Vantage analyzer. Refer to D5421. e) The laboratory failed to perform maintenance on the DCA Vantage analyzer as required by the manufacturer for twelve (12) of twelve (12) months reviewed. Refer to D5429. f) The laboratory failed to establish their own means and ranges for QC material utilized for erythrocyte sedimentation rate (ESR) testing. Refer to D5469. g) The laboratory failed to follow their corrective action policy for quality control when chemistry quality control was outside of acceptable limits for one (1) of one (1) days reviewed. Refer to D5779.
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: Based on observation, review of the laboratory's performance specification records and patient test records, and interview with personnel, the laboratory failed to report patient test results within the reportable range for urine creatinine testing for one (1) of one (1) patient reviewed. Findings: 1. Observation by surveyor during the laboratory tour on August 6, 2025 at 8:40 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the laboratory's performance specification records revealed the laboratory's verified reportable range for urine creatinine was 103.10 to 440.50 mg/dL. 3. Review of a random patient final test report revealed the laboratory reported the following patient test result which exceeded the laboratory's urine creatinine reportable range lower limit: a) Patient Accession ID: 4089963 * Urine Creatinine: 71.00 mg/dL 4. In interview on August 6, 2025 at 4:53 p.m., Testing Personnel 1 confirmed the laboratory reported a patient test result outside of the reportable limit as identified above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance specification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 5. The Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D6024.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for blood collection supplies stored in one (1) of one (1) rooms in the laboratory. Refer to D5413. 2. The laboratory failed to document the open expiration date for Hematology and Chemistry quality control materials. Refer to D5415. 3. The laboratory failed to ensure microbiology specimen collection supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Refer to D5417.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Findings: 1. The laboratory failed to establish their own means and ranges for QC material utilized for erythrocyte sedimentation rate (ESR) testing. Refer to D5469. 2. The laboratory failed to establish complete procedures to identify issues within the analytic system. Refer to D5791.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5779.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation;

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) 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 record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing competency of the Technical Consultant were established. Refer to D5209.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D6043. 5. The Technical Consultant failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for two (2) of four (4) testing personnel reviewed. Refer to D6051.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform assessment activities for unacceptable PT results for two (2) of ten (10) events reviewed. Refer to D5221. 2. The laboratory failed to define acceptable room temperature limits within the manufacturer's required range for blood collection supplies stored in one (1) of one (1) rooms in the laboratory. Refer to D5413. 3. The laboratory failed to document the open expiration date for Hematology and Chemistry quality control materials. Refer to D5415. 4. The laboratory failed to ensure microbiology specimen collection supplies did not exceed their expiration dates in one (1) of one (1) rooms where supplies are stored. Refer to D5417. 5. The laboratory failed to perform maintenance on the DCA Vantage analyzer as required by the manufacturer for twelve (12) of twelve (12) months reviewed. Refer to 5429. 6. The laboratory failed to ensure patient test results that exceeded the laboratory's verified reportable range were reported as less than the reportable range limit for urine creatinine testing for one (1) of one (1) patient reviewed. Refer to D5805.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the 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: Based on observation, records review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5469.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D5779.
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 review of the laboratory's CMS-209 (Laboratory Personnel Report) form, policies, and personnel records; as well as interview with personnel, the Technical Consultant failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for two (2) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed the following testing personnel: a) Personnel 3 b) Personnel 4 c) Personnel 5 d) Personnel 6 2. Review of the laboratory's "Employee Competency Assessment" form revealed six (6) criteria for competency assessment which included "Assessment of test performance (Prof Test/Blinds)." 3. Review of the laboratory's personnel records for Personnel 5 and Personnel 6 revealed the laboratory performed semi-annual competency assessments but failed to provide documentation to support the performance of blind sample testing for the following: a) Personnel 5: Urine microscopic, Sysmex XN, Excyte 10, and Vitros 5600. b) Personnel 6: Urine microscopic and Clinitek Advantus. 4. In interview on August 6, 2025 at 10:55 a.m., Testing Personnel 1 confirmed the laboratory did not have documentation to support blind sample testing as identified above.