Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2247047	11/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care - Veteran's Blvd, The	4517 Veterans Blvd, Suite B, Metairie, 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 The Urgent Care Veteran's Blvd, CLIA ID 19D2247047, on November 6, 2023 through November 7, 2023. The Urgent Care Veteran's Blvd was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1290 CONDITION: Postanalytic 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 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical supervisor 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing; Testing Personnel
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance specification records and interview with personnel, the laboratory failed to retain their Laboratory Information System (LIS) verification records for at least two (2) years. Findings: 1. In interview on October 6, 2023 at 11:53 am, the Technical Consultant stated patient testing began in June 2022. 2. Review of the laboratory's performance specification records revealed the laboratory did not include the following: a) Initial LIS validation to ensure patient results were transmitted accurately for Urinary Tract Infections (UTI) , Sexually Transmitted Infections (STI) and SARS COV-2 testing for two (2) QuantStudio 5 analyzers (Quancy 1 and 2) b) 2023 LIS verification records for STI (Quancy 2) and

	SARS COV-2 (Quancy 1 and 2) testing 3. In interview on October 7, 2023 at 10:23 am, the Technical Consultant confirmed the laboratory did not have documentation of an initial LIS validation in 2022 and the identified records for 2023.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to retain proficiency testing records for at least two (2) years for one (1) of three (3) Microbiology events reviewed in 2023. Findings: 1. Review of the laboratory's "Proficiency Testing Procedures" policy revealed "All records of external PT testing are kept for at least two years." 2. Review of the 2023 American Proficiency Institute (API) proficiency testing (PT) records for the "Microbiology-3rd Event" revealed the laboratory did not retain the supporting documents to include instrument printouts and laboratory data for results submitted for Urinary Tract Infections, Sexually Transmitted Infections and SARS COV-2. 3. In interview on November 6, 2023 at 11am, the Technical Consultant confirmed the Microbiology Event 3 data was not in the proficiency testing binder.
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 review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to successfully verify the accuracy of SARS COV-2 testing at least twice annually in 2023. Findings: 1. Review of the laboratory's "Proficiency Testing Procedures" policy revealed "Two failing events of (2 of 3 consecutive failures) for the same analyte are termed unsuccessful and indicate a fundamental problem with the test method. Corrective action must be vigorously pursued. Effectiveness of corrective action should then be evaluated by ordering additional samples from the provided {sic} by an approved PT program provider. The samples should be tested and submitted to the provider for evaluation. Keep all documentation of corrective action for surveyor review." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2023 revealed the following two (2) unsuccessful events: a) 2023 Microbiology-1st event: SARS COV-2 liquid (molecular), overall score 50% b) 2023 Microbiology-2nd event: SARS COV-2 liquid (molecular), overall score 50% 3. Further review of the laboratory's API proficiency testing records for the two (2) identified events revealed the laboratory did not have documentation of corrective actions or alternate testing to verify the accuracy of SARS COV-2 testing. 4. In interview on November 6, 2023 at 9:37 am, the Technical Consultant confirmed the laboratory did not successfully verify the accuracy of SARS COV-2 test performance at least twice annually in 2023.
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: I. Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform assessment activities for unacceptable Microbiology proficiency testing results for two (2) of three (3) events reviewed in 2023. Findings: 1. Review of the laboratory's "Proficiency Testing Procedures" policy revealed "If the PT is unsatisfactory, corrective action is required. After corrective action is performed, re-test the PT samples for acceptable results. Document all corrective action utilizing the PT provider corrective action worksheet." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records revealed the laboratory did not perform assessments for the following unacceptable results: a) 2023 Microbiology-1st event: QuantStudio System/Bacterial Vaginosis, Sample VGP-01, score: unacceptable QuantStudio System/BVAB-2, Sample VGP-01, score: unacceptable QuantStudio System/Candida glabrata, Sample VGP-02, score: unacceptable QuantStudio System/Candida glabrata-krusei, VGP-02, score: unacceptable b) 2023 Microbiology-2nd event: QuantStudio/Serratia marcescens, Sample UTI-06, score: unacceptable QuantStudio/Klebsiella pneumoniae, Sample UTI-06, score: unacceptable QuantStudio/Morganella morganii, Sample UTI-09, score: unacceptable 3. In interview on November 6, 2023 at 11am, the Technical Consultant confirmed there was no documentation of corrective action for unacceptable Quant studio PT results. II. Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform corrective actions for two (2) unsuccessful proficiency testing events in 2023 for SARS COV-2. Findings: 1. Review of the laboratory's "Proficiency Testing Procedures" policy revealed "If the PT is unsatisfactory, corrective action is required. After corrective action is performed, re-test the PT samples for acceptable results. Document all corrective action utilizing the PT provider corrective action worksheet." 2. Further review of the laboratory's "Proficiency Testing Procedures" policy revealed "Two failing events of (2 of 3 consecutive failures) for the same analyte are termed unsuccessful and indicate a fundamental problem with the test method. Corrective action must be vigorously pursued. Effectiveness of corrective action should then be evaluated by ordering additional samples from the provided {sic} by an approved PT program provider. The samples should be tested and submitted to the provider for evaluation. Keep all documentation of corrective action for surveyor review." 3. Review of the laboratory's 2023 American Proficiency Institute (API) proficiency testing records revealed the laboratory did not have documentation of corrective action, to include, but not limited to patient assessment for the following events: a) 2023 Microbiology-1st event: SARS COV-2 liquid Molecular: Sample: COV-01; score: unacceptable; overall score: 50% b) 2023 Microbiology-2nd event: SARS COV-2 liquid Molecular: Sample: COV-04; score: unacceptable; overall score: 50% 4. In interview on November 6, 2023 at 11am, the Technical Consultant confirmed there was no documentation of corrective action for unacceptable SARS COV-2 PT results.
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 surveyors, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure the Laboratory Director approved the Cepheid GeneXpert procedures. Refer to D5407. 2. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure expired urine transport tubes were not utilized for Microbiology testing for twenty (20) of twenty (20) patients reviewed. Refer to D5417 II. 4. The laboratory failed to verify the performance specifications for Microbiology testing on the Cepheid GeneXpert. Refer to D5421. 5. The laboratory failed to have complete performance specification studies for Microbiology testing on the QuantStudio 5 instruments. Refer to D5423. 6. The laboratory failed to ensure air filter changes for the Air Clean fume hood were performed per manufacturer requirements in 2023. Refer to D5429. 7. The laboratory failed to establish a written maintenance protocol and document performance that included air filter changes for the VWR PCR workstation. Refer to D5433. 8. The laboratory failed to follow control procedures that monitored the accuracy and precision of the complete analytic process for Microbiology testing on the QuantStudio 5 analyzers. Refer to D5441. 9. The laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for Microbiology testing on the GeneXpert instrument. Refer to D5445. 10. The laboratory failed to include a control capable of detecting errors in the extraction phase of Microbiology and Virology testing on the QuantStudio 5 analyzers. Refer to D5453. 11. The laboratory failed to verify the acceptability of QC materials prior to putting into use for Microbiology testing on the QuantStudio analyzers. Refer to D5469. 12. The laboratory failed to perform an instrument comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 I. 13. The laboratory failed to perform a method comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 II. 14. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's procedures, and interview with personnel, the laboratory failed to ensure the Laboratory Director approved the Cepheid GeneXpert procedures. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the laboratory utilizes the Cepheid GeneXpert for Chlamydia trachomatis, Nesierria gonorrhoeae, and Trichomonas vaginalis testing. 2. Review of the laboratory's Cepheid GeneXpert procedures for Microbiology testing revealed the Laboratory Director's signature line was left blank. The Laboratory Director did not approve/sign the identified

	procedures. 3. In interview on November 7, 2023 at 10:16 am, the Technical Consultant confirmed the Laboratory Director did not approve/sign the identified procedures.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on observation by surveyors, review of laboratory policies, and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the following expired items: a) Applied Biosystems 384 well Region of Interest and Background Plates, Expiration date: 2023-07-15, Quantity: one (1) box b) Applied Biosystems 384 well Spectral Calibration Plate, Expiration date: 2023-07-20, Quantity: one (1) box c) DTPM Vacuum urine tubes, Lot 20210726, Expiration date: 2023-07-26, Quantity: twelve (12) boxes 2. Review of the laboratory's policies for high complexity testing on the QuantStudio 5 under the "reagents" section revealed "All reagents, solutions, control materials, calibration materials and other supplies are not used beyond the expiration date, have deteriorated or deemed to be of substandard quality." 3. Review of the laboratory's "Material Management" policy under the "Inventory Control" section revealed "The Laboratory Manager or designee will review the reagent inventory logs at least monthly to determine the need to re-order and the need to remove items from service due to expiration dating." 4. In interview on November 6, 2023 at 9:53 am, Testing Personnel 3 confirmed the identified items were expired. II. Based on observation by surveyors, review of the laboratory's policies, patient test list, and interview with personnel, the laboratory failed to ensure expired urine transport tubes were not utilized for Microbiology testing for twenty (20) of twenty (20) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the patient urine samples received were in expired tubes. The expiration date of the tubes was July 26, 2023. 2. Review of the laboratory's policies for high complexity testing on the QuantStudio 5 under the "reagents" section revealed "All reagents, solutions, control materials, calibration materials and other supplies are: not used beyond the expiration date, have deteriorated or deemed to be of substandard quality. Prepared, stored, and handled in a manner to ensure that reagents, solutions, controls, calibration materials and other supplies, are not used when they have not exceeded their expiration date, have deteriorated or are of substandard quality." 3. Review of the patient test list from November 6, 2023 revealed the following twenty (20) patients were tested and reported after receipt in expired urine transport tubes: Patient 1123K04002 Patient 1123K04003 Patient 1123K04004 Patient 1123K04005 Patient 1123K04006 Patient 1123K04007 Patient 1123K04010 Patient 1123K04012 Patient 1123K04013 Patient 1123K04014 Patient 1123K04015 Patient 1123K05001 Patient 1123K05002 Patient 1123K05003 Patient 1123K05004 Patient 1123K05005 Patient 1123K05006 Patient 1123K05007 Patient 1123K05008 Patient 1123K05009 4. In interview of November 6, 2023 at 9:30 am Testing Personnel 3 stated she was unaware the urine transport tubes were expired.

	Further interview with the Technical Consultant on November 6, 2023 at 2pm confirmed the laboratory provides urine collection tubes to all of the sister sites for specimen transport.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the laboratory's policies, performance specification records, test menu, and interview with personnel, the laboratory failed to verify the performance specifications for Microbiology testing on the Cepheid GeneXpert. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs Microbiology testing on the Cepheid GeneXpert for Chlamydia trachomatis, Nesierria gonorrhoeae, and Trichomonas vaginalis. 2. Review of the laboratory's "Evaluation of Test Methods" policy revealed "The test method evaluation should include a summary of precision, accuracy, linearity for validation of reportable range and patient correlation when applicable. The evaluation should be documented, and all worksheets, instrument printouts, and related documents shall be retained for the life of the method plus two years for regulatory inspection purposes. All documented data must be reviewed and approved by the laboratory director prior to initiating patient testing." 3. Review of the laboratory's performance specification records revealed the laboratory did not perform studies that included the following: a) Accuracy b) Precision, to include day-to-day, run-to-run, within-run and operator variance c) Reference range d) Reportable range e) Laboratory Director's review/approval 4. In interview on October 6, 2023 at 11:53 am, the Technical Consultant stated patient testing on the Cepheid GeneXpert started June 2022. The Technical Consultant further stated the laboratory performed the verification panel for the GeneXpert on September 20, 2023. The Technical Consultant stated a summary of their validation (performance specification) studies needed to be written. The Technical Consultant confirmed the laboratory did not verify the performance specifications for Microbiology testing on the Cepheid GeneXpert prior to patient testing in June 2022 because of an inability to obtain supplies from the manufacturer. 5. Further review of the laboratory's test menu revealed the laboratory performs 120 Chlamydia trachomatis, 120 Neisseria gonorrhoeae, and forty (40) Trichomonas vaginalis tests annually.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's performance specification records, test menu, and interview with personnel, the laboratory failed to have complete performance specification studies for Microbiology testing on the QuantStudio 5 instruments. Findings: 1. Observation by surveyors during the laboratory tour on October 6, 2023 at 9:30 am revealed the laboratory utilizes two (2) Quant Studio 5 instruments for Sexually Transmitted Infections (STI), Urinary Tract Infections (UTI), and SARS COV-2 testing. 2. Review of the laboratory's performance specification studies revealed the laboratory did not include the following: a) Analytical sensitivity: supporting laboratory data for limit of detection b) Establishment of quantitative test method for STI, UTI, and SARS COV-2 testing 3. In interview on October 6, 2023 at 1:35 pm, the Technical Consultant confirmed the laboratory's performance specification studies did not include the identified performance characteristics. 4. Review of the laboratory's test menu revealed the laboratory performs 43,700 Microbiology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 by surveyors, review of the manufacturer's user manual, maintenance logs, and interview with personnel, the laboratory failed to ensure air filter changes for the Air Clean fume hood were performed per manufacturer requirements in 2023. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the laboratory utilizes an Air Clean 600 PCR workstation. 2. Review of the user manual for the Air Clean 600 fume hood revealed the following maintenance requirements: a) "Pre-filters should be inspected for dust/particulate saturation every month. With average use, the pre-filters should be changed every 3 months." b) "HEPA filters should be changed every 18-24 months or when the alarm sounds, whichever comes first." 3. Review of the laboratory's maintenance logs for 2023 revealed the laboratory did not document the performance of monthly pre-filter changes for the identified fume hood. Further review revealed no frequency for HEPA filter change determined by the laboratory. 4. In interview on November 7, 2023 at 10:31 am, Testing Personnel 3 confirmed the monthly prefilter changes for the Air Clean fume hood are not documented, and personnel was not aware a second filter needed to be maintained.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check

	protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, manufacturer's manual, maintenance records, and interview with personnel, the laboratory failed to establish a written maintenance protocol and document performance that included air filter changes for the VWR PCR workstation. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the laboratory utilizes the VWR PCR workstation. 2. Review of the manufacturer's manual revealed the manufacturer did not include air filter change procedures. 3. In interview on November 7, 2023 at 10:31 am, Testing Personnel 3 stated she changes the filter every three (3) months on the VWR PCR workstation. 4. Review of the laboratory's 2023 fume hood maintenance log revealed filter changes were not documented. 5. In further interview on November 7, 2023 at 10:31 am, Testing Personnel 3 confirmed the laboratory did not have a written maintenance protocol or documentation of filter changes for the identified VWR PCR workstation.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of quality control (QC) records, and interview with personnel, the laboratory failed to follow control procedures that monitored the accuracy and precision of the complete analytic process for Microbiology testing on the QuantStudio 5 analyzers. Findings: 1. Review of the laboratory's "UTI" and "STI" policies under the "Quality Control Samples" section revealed "Acceptability of the positive controls is dependent upon the agreement of the Ct values +/- 20% (80% -120%) as determined through continual charting. Once a week, a QC plate (containing all the validated molecular assays on that instrument) will be run to confirm the stability of the chemistry and all analytical systems for all assays. Acceptability of QC results for each analyte is dependent upon the agreement of the Ct values +/-20% (80%-120%) as determined through quality control continual charting. Acceptable averaged Ct values must maintain +/- 20% (80%-120%) accuracy during continual charting. If the Ct value for either a daily positive control or a weekly QC are outside of the acceptable limits, the results are rejected and the following steps will be taken with QC results rechecked after each is performed." 2.

	Review of the laboratory's weekly QC records for September 2023 revealed the laboratory did not evaluate the control values to ensure the +/-20% agreement limit was met as required by the laboratory policy. 3. In interview on November 6, 2023 at 1:39 pm, Testing Personnel 3 stated when she reviews the positive QC she makes sure the daily values fall within the acceptable Ct value range of 15-35 and was unaware of the additional +/- 20% agreement criteria detailed in the policy.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's Individualized Quality Control Plan (IQCP) records, and interview with personnel, the laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for Microbiology testing on the GeneXpert instrument. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the laboratory utilizes the GeneXpert instrument for testing of Trichomonas vaginalis, Chlamydia trachomatis, and Neisseria gonorrhoeae. 2. Review of the laboratory's IQCP for the identified Microbiology testing revealed "External controls will be assayed with each new lot, each new shipment and every 25-30 days after the lot /shipment is in use, as well as after system maintenance and software upgrades." 3. Further review of the laboratory's IQCP records revealed the laboratory did not include the following: a) Quality control data to support reduction to every thirty (30) days b) Laboratory Director's review/approval 4. In interview on November 6, 2023 at 11:42 am, the Technical Consultant confirmed the laboratory did not include quality control data to support the reduction to every thirty (30) days and that the Laboratory Director had not approved the IQCP.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the laboratory failed to include a control capable of detecting errors in the extraction phase of Microbiology and Virology testing on the QuantStudio 5

	analyzers. Findings: 1. Observation by surveyors during the laboratory tour on November 6, 2023 at 9:30 am revealed the laboratory utilizes two (2) QuantStudio 5 analyzers for Microbiology and Virology testing. 2. Review of the laboratory's QC policies for testing on the QuantStudio 5 revealed "A 'no template' (negative) control (NTC) is included in each run and taken through the full sample processing procedure starting with extraction" 3. In interview on November 7, 2023 at 11:25 am, Testing Personnel 3 stated the negative control is molecular grade water, but it does not go through the extraction phase.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's quality control (QC) policies, QC records, and interview with personnel, the laboratory failed to verify the acceptability of QC materials prior to putting into use for Microbiology testing on the Quant Studio analyzers. Findings: 1. Observation by surveyors on November 7, 2023 at 10am revealed the laboratory received QC material from DTPM for testing performed on the Quant Studio. 2. Review of the laboratory's policies revealed the laboratory did not include a written policy detailing process for verification of new lots of QC materials prior to use for patient testing. 3. Review of QC records revealed the laboratory did not verify the acceptability of the following lots of positive QC material prior to patient use: a) UTI PD990012 Panel, Kit #599 b) STI PD99011 Panel, Kit #487 4. In interview on November 7, 2023 at 10:43 am, Testing Personnel 3 confirmed the laboratory did not have a process to verify the acceptability of new lots of QC material prior to use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, records, test menu, and interview with

	personnel, the laboratory failed to perform an instrument comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Findings: 1. Review of the laboratory's test menu revealed the laboratory tests for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis on two (2) QuantStudio 5 instruments. 2. In interview on November 6, 2023 at 11:53 am, the Technical Consultant stated Microbiology patient testing began June 2022. 3. Review of the laboratory's policies under the "Evaluation of Test Methods" section revealed "Method comparison studies are performed to determine the relative bias (accuracy) between the method under evaluation and the method currently in use, if another method or analyzer is being used in the laboratory." 4. Review of the laboratory's records revealed the laboratory did not perform an instrument comparison due December 2022 and June 2023, for the identified Microbiology testing. 5. In interview on November 7, 2023 at 2:10 pm, the Technical Consultant confirmed the laboratory did not perform instrument comparisons for the identified Microbiology testing. II. Based on review of the laboratory's policies, records, test menu, and interview with personnel, the laboratory failed to perform a method comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Findings: 1. Review of the laboratory's test menu revealed the laboratory tests for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis on two (2) QuantStudio 5 instruments and the Cepheid GeneXpert. 2. In interview on November 6, 2023 at 11:53 am, the Technical Consultant stated Microbiology patient testing began June 2022. 3. Review of the laboratory's policies under the "Evaluation of Test Methods" section revealed "Method comparison studies are performed to determine the relative bias (accuracy) between the method under evaluation and the method currently in use, if another method or analyzer is being used in the laboratory." 4. Review of the laboratory's records revealed the laboratory did not perform a method comparison, due December 2022 and June 2023, for the identified Microbiology testing. 5. In interview on November 7, 2023 at 2:10 pm, the Technical Consultant confirmed the laboratory did not perform a method comparison for the identified Microbiology testing.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records, quality assessment records, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's monthly "QA Checklist" revealed the laboratory monitors the following: a) Quality Assurance that includes review of documented remedial actions b) Quality Control 2. Observation by surveyors, review of laboratory records and interview with personnel revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to ensure the Laboratory Director approved the Cepheid GeneXpert procedures. Refer to D5407. b) The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417 I. c) The laboratory failed to ensure expired urine transport tubes were not utilized for Microbiology testing for twenty (20) of twenty (20)

	patients reviewed. Refer to D5417 II. d) The laboratory failed to verify the performance specifications for Microbiology testing on the Cepheid GeneXpert. Refer to D5421. e) The laboratory failed to have complete performance specification studies for Microbiology testing on the QuantStudio 5 instruments. Refer to D5423. f) The laboratory failed to ensure air filter changes for the Air Clean fume hood were performed per manufacturer requirements in 2023. Refer to D5429. g) The laboratory failed to establish a written maintenance protocol and document performance that included air filter changes for the VWR PCR workstation. Refer to D5433. h) The laboratory failed to follow control procedures that monitored the accuracy and precision of the complete analytic process for Microbiology testing on the QuantStudio 5 analyzers. Refer to D5441. i) The laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for Microbiology testing on the GeneXpert instrument. Refer to D5445. j) The laboratory failed to include a control capable of detecting errors in the extraction phase of Microbiology and Virology testing on the QuantStudio 5 analyzers. Refer to D5453. k) The laboratory failed to verify the acceptability of QC materials prior to putting into use for Microbiology testing on the QuantStudio analyzers. Refer to D5469. l) The laboratory failed to perform an instrument comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 I. m) The laboratory failed to perform a method comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 II.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with personnel, the laboratory failed to ensure the overall quality of the postanalytic systems. Findings: 1. The laboratory failed to include on the patient final test report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by The Urgent Care-Veteran's Blvd. It has not been cleared or approved by the U.S. Food and Drug Administration" for four (4) of four (4) patient final reports reviewed. Refer to D5805 I. 2. The laboratory failed to report qualitative results per their performance specification studies for Microbiology testing on the QuantStudio instruments. Refer to D5805 II. 3. The laboratory failed to include the correct CLIA identification number of the testing laboratory for four (4) of four (4) patient reports reviewed for Microbiology testing on the QuantStudio instruments. Refer to D5805 III. 4. The laboratory failed to included reference ranges on patient final test reports for Microbiology testing. Refer to D5807.
D5805	TEST REPORT CFR(s): 493.1291(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 review of patient final test reports, test menu, and interview with personnel, the laboratory failed to include on the patient final test report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by The Urgent Care-Veteran's Blvd. It has not been cleared or approved by the U.S. Food and Drug Administration" for four (4) of four (4) patient final reports reviewed. Findings: 1. Review of random selection of the following four (4) patient final test reports revealed the laboratory did not include the above disclaimer: Patient 1: STI Panel reported 2023-08-09 Patient 2: STI Panel reported 2023-08-09 Patient 3: UTI Panel reported 2023-08-21 Patient 4: STI Panel reported 2023-11-03 2. In interview on November 7, 2023 at 11am, the Technical Consultant stated she was unaware the final report included no indication the test was not FDA approved. 3. Review of the laboratory's test menu revealed the laboratory performs 43,700 Microbiology tests annually on the QuantStudio 5. II. Based on review of the laboratory's policies, performance specification records, patient final test reports, and interview with personnel, the laboratory failed to report only qualitative results per their performance specification studies for Microbiology testing on the QuantStudio instruments. Findings: 1. Review of the laboratory's "Method Validation" records for testing performed on the Quant Studio revealed "Our qualitative clinical assays with detected/not detected thresholds are not determined by the inherent detection limit of the method, but by predetermined threshold value that limits false positive results." 2. Review of the laboratory's "UTI and STI SOPs" stated "However, the assays encompassing the scope of this method are reported using only qualitative criteria with no [explicit or implied] suggestion of magnitude, quantity, or intensity related to the detection of any target." 3. Review of a random selection of patient final reports for Microbiology testing on the QuantStudio 5 instruments revealed the laboratory reported both qualitative and quantitative results for the following patients: Patient 1: STI Panel reported 2023-08-09 Patient 2: STI Panel reported 2023-08-09 Patient 3: UTI Panel reported 2023-08-21 Patient 4: STI Panel reported 2023-11-03 4. In interview on November 7, 2023 at 11:51 am, Testing Personnel 3 confirmed the laboratory reported qualitative and quantitative results. III. Based on review of the laboratory's CLIA certificate, patient final test reports, and interview with personnel, the laboratory failed to include the correct CLIA identification number of the testing laboratory for four (4) of four (4) patient reports reviewed for Microbiology testing on the QuantStudio instruments. Findings: 1. Review of the laboratory's CLIA certificate and random selection of the following four (4) patient final test reports revealed the laboratory included the wrong CLIA identification number: Patient 1: STI Panel reported 2023-08-09 Patient 2: STI Panel reported 2023-08-09 Patient 3: UTI Panel reported 2023-08-21 Patient 4: STI Panel reported 2023-11-03 2. In interview on November 7, 2023 at 11:00 am, the Technical Consultant confirmed the laboratory did not include the correct CLIA identification number on their patient final reports.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of random selection of patient final test reports, test menu, and interview with personnel, the laboratory failed to included reference ranges on patient final test reports for Microbiology testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs Microbiology testing (UTI and STI panels) on two (2) QuantStudio 5 instruments and Chlamydia, Gonorrhoeae, and Trichomonas testing on the Cepheid GeneXpert instrument. 2. Review of random selection of the following five (5) patient final test reports for Microbiology testing revealed the laboratory did not include the reference ranges: Patient 1: STI Panel reported 2023-08-09 Patient 2: STI Panel reported 2023-08-09 Patient 3: UTI Panel reported 2023-08021 Patient 4: STI Panel reported 2023-11-03 Patient 254154 Cepheid GeneXpert testing 3. In interview November 7, 2023 at 11:51 am, the Technical Consultant confirmed the reference ranges were not included on patient final test reports. 4. Further review of the laboratory's test menu revealed the laboratory performs 43,7000 Micrbiology tests on the QuantStudio 5 and 244 GeneXpert testing annually.
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 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 a quality control program was established to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on observation by surveyors, 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) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (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 review of the laboratory's records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5775 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5807.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 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 ensure performance specification verification studies were performed. Refer to D6040. 2. The Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6042.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were performed. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (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 review of the laboratory's quality control records and interview with personnel, the Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5445.
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 observation by surveyors, 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 establish complete performance specifications for testing. Refer to D6086. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure the laboratory documented complete corrective actions for unacceptable proficiency testing results. Refer to D6092. 4. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6094. 6. The Laboratory Director failed to ensure maintenance procedures were established and followed to ensure acceptable levels of test performance. Refer to D6095. 7. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6098. 8. The Laboratory Director failed to ensure two (2)

	Testing Personnel reviewed had the appropriate state of Louisiana license prior to patient testing. Refer to D6102. 9. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6103.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's performance specification studies, test menu, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 by surveyors and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to retain their Laboratory Information System (LIS) verification records for at least two (2) years. Refer to D3033. 2. The laboratory failed to retain proficiency testing records for at least two (2) years for one (1) of three (3) events reviewed in 2023. Refer to D3037. 3. The laboratory failed to successfully verify the accuracy of SARS COV-2 testing at least twice annually in 2023. Refer to D5217. 4. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417 I. 5. The laboratory failed to ensure expired urine transport tubes were not utilized for Microbiology testing. Refer to D5417 II. 6. The laboratory failed to perform an instrument comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 I. 7. The laboratory failed to perform a method comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 II.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is 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 documented complete corrective actions for unacceptable proficiency testing results. Findings: 1. The laboratory failed to perform assessment activities for unacceptable Microbiology proficiency testing results for two (2) of three (3) events reviewed in 2023. Refer to D5221 I. 2. The laboratory failed to

	perform corrective actions for two (2) unsuccessful proficiency testing events in 2023 for SARS COV-2. Refer to D5221 II.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish complete QC procedures for Microbiology testing on the QuantStudio 5 analyzers. Refer to D5441. 2. The laboratory failed to include a control capable of detecting errors in the extraction phase of Microbiology and Virology testing on the QuantStudio 5 analyzers. Refer to D5453. 3. The laboratory failed to verify the acceptability of QC materials prior to putting into use for Microbiology testing on the QuantStudio analyzers. Refer to D5469.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 by surveyors, review of the manufacturer's manual, maintenance records, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were established and followed to ensure acceptable levels of test performance. Findings: 1. The laboratory failed to ensure air filter changes for the Air Clean fume hood were performed per manufacturer requirements. Refer to D5429. 2. The laboratory failed to establish a written maintenance protocol and document performance that included air filter changes for the VWR PCR workstation. Refer to D5433.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Findings: 1. The laboratory failed to include on the patient final test report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by Foot Health Center, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration" for four (4) of four (4) patient final reports reviewed. Refer to D5805 I. 2. The laboratory failed to report qualitative results per their performance specification studies for Microbiology testing on the QuantStudio instruments. Refer to D5805 II. 3. The laboratory failed to include the correct CLIA identification number of the testing laboratory for four (4) of four (4) patient reports reviewed for Microbiology testing on the QuantStudio instruments. Refer to D5085 III. 4. The laboratory failed to included reference ranges on patient final test reports for Microbiology testing. Refer to D5807.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the Laboratory Director failed to ensure two (2) of three (3) Testing Personnel reviewed had the appropriate state of Louisiana license prior to patient testing. Refer to D6170.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6120.

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 observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 2. The Technical Supervisor failed to ensure the laboratory established complete performance studies. Refer to D6115. 3. The Technical Supervisor failed to ensure proficiency samples are tested as required. Refer to D6116. 4. The Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of Microbiology testing. Refer to D6117. 5. The Technical Supervisor failed to have supporting documentation that included the six (6) minimal assessment requirements for semi-annual and annual competency assessments for three (3) of three (3) high complexity testing personnel. 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 observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to retain their Laboratory Information System (LIS) verification records for at least two (2) years. Refer to D3033. 2. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure expired urine transport tubes were not utilized for Microbiology testing. Refer to D5417 II. 4. The laboratory failed to ensure air filter changes for the Air Clean fume hood were performed per manufacturer requirements. Refer to D5429. 5. The laboratory failed to establish a written maintenance protocol and document performance that included air filter changes for the VWR PCR workstation. Refer to D5433. 6. The laboratory failed to perform an instrument comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 I. 7. The laboratory failed to perform a method comparison for Microbiology testing at least twice a year from June 2022 through November 2023. Refer to D5775 II.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's 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 by surveyors, review of the performance specification studies, test menu, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies. Refer to D5423.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the Technical Supervisor failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to retain proficiency testing records for at least two (2) years for one (1) of three (3) events reviewed in 2023. Refer to D3037. 2. The laboratory failed to successfully verify the accuracy of SARS COV-2 testing at least twice annually in 2023. Refer to D5217. 3. The laboratory failed to perform assessment activities for unacceptable Microbiology proficiency testing results for two (2) of three (3) events reviewed in 2023. Refer to D5221 I. 4. The laboratory failed to perform corrective actions for two (2) unsuccessful proficiency testing events in 2023 for SARS COV-2. Refer to D5221 II.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for 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 record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of Microbiology testing. Findings: 1. The laboratory failed to establish complete QC procedures for Microbiology testing on the QuantStudio 5 analyzers. Refer to D5441. 2. The laboratory failed to include a control capable of detecting errors in the extraction phase of Microbiology and Virology testing on the QuantStudio 5 analyzers. Refer to D5453. 3. The laboratory failed to verify the acceptability of QC materials prior to putting into use for Microbiology testing on the QuantStudio analyzers. Refer to D5469.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (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 personnel competency assessment records and interview with personnel, the Technical Supervisor failed to include the six (6) minimal assessment requirements for semi-annual and annual competency assessments for three (3) of three (3) high complexity testing personnel. Findings: 1. Review of the laboratory's personnel competency assessment records revealed a checklist form titled "Clinical Laboratory Technician Assessment of Competency." The form included the following six (6) methods of evaluation: direct observation, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, direct observation of instrument maintenance, proficiency testing, and assessment of problem solving skills. 2. Review of the laboratory's personnel records revealed the laboratory utlized an alternate check-list that did not include documentation of the six (6) methods of evaluation for competency assessments for the following three (3) testing personnel: a) Testing Personnel 3: semi-annual (January 2023) and 2023 annual (July 2023) b) Testing Personnel 4: semi-annual (January 2023) and 2023 annual (July 2023) c) Testing Personnel 5: semi-annual (January 2023) and 2023 annual (July 2023); previously employed personnel 3. Further review of the testing personnel records revealed blank forms for each of the 6 methods of evaluation for competency assessment in each personnel section. 3. In interview on November 6, 2023 at 3pm, the Technical Consultant stated she was not involved in the high complexity competency assessments and could not identify how competency was determined or if the 6 assessment criteria were utilized.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report), personnel records, and interview with personnel, the laboratory failed to ensure Testing Personnel met state licensure requirements for high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the laboratory failed to ensure two (2) of five (5) testing personnel

	met the state of Louisiana licensure requirement to perform high complexity testing in Microbiology. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Record) and personnel records revealed the following two (2) personnel did not have a state of Louisiana license for high complexity testing in Microbiology: a) Testing Personnel 3: laboratory assistant license b) Testing Personnel 5: Clinical Laboratory Scientist-Specialist license in Chemistry 2. In interview on November 7, 2023, Testing Personnel 3 and the Technical Consultant confirmed the license status provided for personnel.