Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0462715	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baton Rouge Urology Group	7777 Hennessy Blvd Suite 2004, Baton Rouge, 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 Certification survey was performed at Baton Rouge Urology Group, CLIA ID # 19D9462715. Baton Rouge Urology 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 42 CFR 493.1441: CONDITION: Laboratories Performing High Complexity Testing; Laboratory Director 42 CFR 493.1447: CONDITION: Laboratories Performing High Complexity Testing; Technical Supervisor
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: **Repeat deficiency from survey performed on February 16, 2022 ** Based on review of the laboratory's policy, proficiency testing records, and interview with personnel, the laboratory failed to document assessment for unacceptable Routine Chemistry proficiency scores for one (1) out of five (5) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Policy" revealed "Any result that fails to meet the expected and/or acceptable criteria (anything less than 100 %) initiates a Corrective Action. Each event requires its own set of Corrective Action steps, which may or may not include: 1) Review of Calibration and Quality Control results for the

	date of analysis 2) Consider reagent issues 3) Consider instrument service 4) Review of all patient results for that particular day 5) All relative patient charts for that day may be pulled and the physician consulted regarding patient results for specific test(s) on that day, and the potential effect for each particular patient 6) Any and all actions performed in response to these issues must be documented." 2. Review of the 2022 and 2023 proficiency testing records revealed the laboratory did not document an assessment for the following unacceptable score: a) American Academy of Family Physicians (AAFP): 2022 Event C: Sodium , Sample: CH-12N, Result: Fail; Score: 80% 3. In interview on October 24, 2023 at 12:17 pm the Technical Consultant confirmed the laboratory did not have documentation of an assessment for the identified unacceptable score.
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 and interview with personnel, the laboratory failed to establish complete policies and procedures to assess competency of laboratory personnel. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a detailed written policy that included the frequency of performance and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Further review of the laboratory's policies revealed the laboratory did not include the frequency of performance of competency assessments for personnel serving as Technical Consultant, Technical Supervisor, and General Supervisor. 3. In interview on October 24, 2023 at 2:10 pm, the Technical Consultant confirmed the laboratory did not have written policies related to competency assessments for laboratory personnel.
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, proficiency testing records, and interview with personnel, the laboratory failed to perform an assessment for unacceptable proficiency testing results for three (3) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Policy" revealed "Any result that fails to meet the expected and/or acceptable criteria

	(anything less than 100 %) initiates a Corrective Action. Each event requires its own set of Corrective Action steps, which may or may not include: 1) Review of Calibration and Quality Control results for the date of analysis 2) Consider reagent issues 3) Consider instrument service 4) Review of all patient results for that particular day 5) All relative patient charts for that day may be pulled and the physician consulted regarding patient results for specific test(s) on that day, and the potential effect for each particular patient 6) Any and all actions performed in response to these issues must be documented." 2. Review of the 2022 and 2023 proficiency testing records revealed the laboratory did not document an assessment for the following unacceptable scores: a) American Academy Family Physicians (AAFP): 2022-C: Urine Culture Susceptibility Cephalothin, Sample: UC-11; Result: Fail; Score: 0% b) American Academy Family Physicians (AAFP): 2022-C: Urine Culture, Sample: UC-12, Score: Fail; Sample: UC-15, Result: Fail; Score: 60% c) American Proficiency Institute (API): 2023 Chemistry Core 1st Event: PSA, Sample: IA-01; Performance: Unacceptable; Score: 50%. Laboratory had incomplete documentation of corrective actions. d) American Proficiency Institute (API): 2023 Microbiology 2nd Event: Urine Culture Susceptibility Interpretation: Agar Disk Diffusion/CLSI/Ciprofloxacin, Sample: UR-06; Result Unacceptable; Score: 80% 3. Further review of the laboratory's API 2023 Chemistry Core 1st Event proficiency testing records revealed the following: "PSA failure-repeat on new lot of reagent on 2 /22/23 new result within limits." The laboratory did not have documentation of review of patient charts. 4. In interview on October 24, 2023 at 12:03 pm, the Technical Consultant confirmed the laboratory did not perform patient chart reviews for the PSA PT failure. 5. In further interview on October 24, 2023 at 12:17 pm the Technical Consultant confirmed the laboratory did not have documentation of assessments for the identified unacceptable scores.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Findings: 1. In interview on October 24, 2023 at 1:05 pm, the Technical Consultant stated the laboratory receives samples from satellite clinics. 2. Review of the laboratory's policies revealed the laboratory did not have detailed written instructions for providers that included the following: a) Patient preparation. b) Specimen collection. c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. d) Specimen storage and preservation. e) Conditions for specimen transportation. f) Specimen processing. g) Specimen acceptability and rejection. h) Specimen referral. 2. In further interview on October 24, 2023 at 1:05 pm, the Technical Consultant confirmed the laboratory did not have written instructions for providers related to specimen handling.
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 the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies. Refer to D5403. 3. The laboratory failed to ensure the Complete Blood Count (CBC) procedures were approved and signed by the laboratory director. Refer to D5407. 4. The laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Refer to D5413. 5. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417. 6. The laboratory failed to have complete verification of performance specifications for Complete Blood Count (CBC) testing on the Medonic M series analyzer. Refer to D5421. 7. The laboratory failed to perform quality control checks weekly, per laboratory policy, to ensure the media's ability to support growth for two (2) of fourteen (14) weeks reviewed. Refer to D5477. 8. The laboratory failed to ensure quality control mean/range adjustments were documented for Chemistry testing. Refer to D5481. 9. The laboratory failed to ensure the sizes of control zones were within established limits for antimicrobial susceptibility testing for thirteen (13) of fourteen (14) weeks reviewed in 2023. Refer to D5507. 10. The laboratory failed to ensure assessment activities for performance of calibration for Chemistry testing were effective in correcting issue identified. Refer to D5793 I. 11. The laboratory's quality assurance monitors failed to identify and correct issues within the analytic system. D5793 II.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Performance specification: complete procedures that included precision (day-to-day, run-to-run, and within-run, as well as, operator variance) and reference range studies b) Complaint Investigations to include how to address, document, and handle complaints or problems reported to the laboratory c) Record retention requirements d) Complete Blood Counts (CBC) flagging issues that occur on the Medonic M-series instrument, to include what alternate methods/actions are required 2. In interview on October 24, 2023 at 2:10 pm, the Technical Consultant confirmed the laboratory did not include the identified policies in their procedure manual.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include the following: a) Quality Control to include, but not limited to: The frequency of performance, how to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material b) Corrective action procedures for quality control failures c) Reporting of panic/critical values d) Course of action if test system becomes inoperable 2. In interview on October 24, 2023 at 2:10 pm, the Technical Consultant confirmed the laboratory did not include the identified policies in their procedure manual.
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 review of the laboratory's policy and interview with personnel, the laboratory failed to ensure the Complete Blood Count (CBC) procedures were approved and signed by the Laboratory Director. Findings: 1. In interview on October 24, 2023 at 1:19 pm the Technical Consultant stated the laboratory uses the manufacturer's manual for their operating procedures for CBC testing on the Medonic M series instrument. 2. Review of the manufacturer's manual CBC procedures revealed the Laboratory Director did not review/approve the procedures. 3. In further interview on October 24, 2023 at 1:19 pm the Technical Consultant confirmed the Laboratory Director did not sign the CBC procedures.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 by surveyor, review of manufacturers' requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on October 24, 2023 at 10:16 am revealed the laboratory stored the following supplies in a storage room without monitoring the room temperature: a) Multistix 10SG Urine Strips: lot 304036, Quantity: eleven (11) boxes b) BD Vacutainer SST blood collection tubes: lot 3215461, Quantity: one (1) pack; lot 3223269, Quantity: nine (9) packs c) BD Vacutainer serum blood collection tubes: lot 2278093, Quantity: two (2) packs d) BD PST Gel and Lithium heparin blood collection tubes: lot 3048768, Quantity: two (2) packs e) BD Vacutainer K2EDTA blood collection tubes: lot 3136174, Quantity: one (1) pack; lot 3111814, Quantity: two (2) packs; lot 3074275, Quantity: one (1) pack 2. Review of the manufacturers' storage requirements revealed the following: a) Multistix 10SG Urine strips: 15-30 degrees Celsius b) BD Vacutainer blood collection tubes: 4-25 degrees Celsius 3. In interview on October 24, 2023 at 10:16 am, the Technical Consultant confirmed the laboratory did not monitor the room temperature of the storage room where the identified items were stored.
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: **Repeat deficiency from survey conducted on February 16, 2022** Based on observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 24, 2023 at 10:16 am revealed the following expired items: a) Gastrointestinal Pathogen Panel Rectal Swab kits, lot 220754800, Expiration date: 2023-07-31, Quantity: thirteen (13) boxes b) CTS Preservation Urine Tubes, lot 1349502, Expiration date: 2023-06-30, Quantity: one (1) pack 2. In interview on October 24, 2023 at 10:26 am, the Technical Consultant confirmed the identified items were expired
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 observation by surveyor, review of the laboratory's performance specification records, test menu, and interview with personnel, the laboratory failed to have complete verification of performance specifications for Complete Blood Count (CBC) testing on the Medonic M series analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 24, 2023 at 10:16 am revealed the laboratory utilizes the Medonic analyzer for CBC testing. 2. Review of the laboratory's "Medonic M Series Method Validation Evaluation" revealed the laboratory did not include the following: a) Precision: to include day-to-day and operator variance b) Reference range studies to include, but not limited to, verification studies, supporting raw data, and ranges in use c) Acceptability of performance specification studies by the Laboratory Director 3. In interview October 24, 2023 at 12:32 pm, the Technical Consultant confirmed the laboratory did not include the identified items in their performance specification studies for CBC testing. 4. Review of the laboratory's test menu revealed the laboratory performs 10,338 CBC tests annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's microbiology quality control records and interview with personnel, the laboratory failed to perform quality control checks weekly, per laboratory policy, to ensure the media's ability to support growth for two (2) of fourteen (14) weeks reviewed. Findings: 1. In interview on October 24, 2023 at 2:00 pm, Testing Personnel 1 stated the laboratory performs quality control for microbiology testing weekly. 2. Review of random selection of "Microbiology Quality Control" logs in 2023 revealed the laboratory did not document the ability to support growth for the following: a) Week January 3-6, 2023: Mueller hinton: growth /no growth was not documented for Pseudomonas, Escherchia coli (E. coli), and Staphyloccous aureus (S .aureus) b) Week of January 16-20, 2023: Mueller hinton: growth/no growth was not documented for Pseudomonas, Escherchia coli (E. coli), and Staphyloccous aureus (S.aureus) TSA with blood: growth/no growth was not

	documented for Enterococcus 3. In interview on October 24, 2023 at 2:00 pm, Testing Personnel 1 stated the identified quality control that was not documented was an oversight.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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, quality control records, and interview with personnel, the laboratory failed to ensure quality control mean/range adjustments were documented for Chemistry testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a detailed quality control policy that included, but not limited to, frequency of performance, establishment of means /ranges, and monitoring. 2. In interview on October 24, 2023 at 2:47 pm, the Technical Consultant stated the laboratory uses BioRad controls for Chemistry testing and documents adjustments on the "Vitros 350 Temporary Mean Set For New Slide Lot" form. 3. Review of the laboratory's "Vitros 350 Temporary Mean Set For New Slide Lot" that included QC lot # 45890 and 45960 revealed the laboratory did not include the date of the mean and range adjustments or supporting raw data for adjustments made to lot # 45890 for glucose and creatinine. 4. In further interview on October 24, 2023 at 2:47 pm, the Technical Consultant confirmed the laboratory did not have a written quality control policy that included mean/range adjustments and dates of the adjustments were not documented.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, microbiology quality control logs, manufacturer's package insert, test menu, and interview with personnel, the laboratory failed to ensure the sizes of control zones were within established limits for antimicrobial susceptibility testing for thirteen (13) of fourteen (14) weeks reviewed in 2023. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a detailed written quality control policy for Bacteriology testing that included corrective actions. 2. In interview on October 24, 2023 at 2:00 pm, Testing Personnel 1 stated the laboratory performs QC on the antimicrobial discs weekly. 3. Review of the "BD BBL Sensi-Disc Antimicrobial Susceptibility Test Disc" package insert revealed "If the disc form incorrect zones with the recommended control organisms,

the entire procedure should be checked; faulty zone size may be due to the disc, the inoculation, the preparation or depth (about 4 mm) of medium, or other factors." 4. Further review of the "BD BBL Sensi-Disc Antimicrobial Susceptibility Test Disc" package insert revealed Enterococcus (ATCC 29212) was not listed as a control organism with control zone limits. The package insert listed Enterococcus (ATCC 29212) as a control organism for gentamicin 120 ug and streptomycin, which were not listed as dics utilized by the laboratory. 5. In interview on October 24, 2023 at 2:16 pm, the Technical Consultant stated she was unsure of where the control zone ranges for Enterococcus (ATCC 29212) utilized with the BD BBL Sensi-Disc came from. 6. Review of random selection of 2023 "Microbiology Quality Control" logs revealed the following unacceptable zones with control organisms without documentation of corrective actions: a) Week of January 3-6, 2023: Enterococcus (ATCC 29212): Ampicillin: zone size reported 24 (acceptable range 17-22); Ciprofloxacin: zone size reported 16 (acceptable range 21-33); Levofloxacin: zone size reported 17 (acceptable range 19-22) b) Week of January 9-13, 2023: Pseudomonas: Piperacillin (ATCC 27853): zone size reported 24 (acceptable range 25-33) Staphylococcus aureus (S. aureus) (ATCC 25923): Nitrofurantoin: reported zone size 17 (acceptable range 18-22) Enterococcus (ATCC 29212): Ampicillin: zone size reported 26 (acceptable range 17-22); Ciprofloxacin: zone size reported 17 (acceptable range 21-33); Levofloxacin: zone size reported 17 (acceptable range 19-22) c) Week of January 23-27, 2023: Enterococcus (ATCC 29212): Ampicillin: zone size reported 25 (acceptable range 17-22) d) Week of January 30-February 3, 2023: S. aureus (ATCC 25923): Nitrofurantoin: zone size reported 17 (acceptable range 18-22); Vancomycin zone size reported 16 (acceptable range 17-21) Enterococcus (ATCC 29212): Ampicillin: zone size reported 24 (acceptable range 17-22); Levofloxacin: zone size reported 15 (acceptable range 19-22) e) Week of May 1-5, 2023: Pseudomonas (ATCC 27853): Gentamicin: zone size reported 23 (acceptable range 16-21); Escherichia coli (E. coli) (ATCC 25922): Cephalosporin 3rd: zone size reported 21 (acceptable range 23-28) S. aureus (ATCC 25923): Tetracycline: zone size reported 34 (acceptable range 24-30); Vancomycin: zone size reported 22 (17-21) Enterococcus (ATCC 29212): Ciprofloxacin: zone size reported 19 (acceptable range 21-33) f) Week of May 5-12, 2023: S. aureus (ATCC 25923): Nitrofurantoin: zone size reported 17 (acceptable range 18-22); Vancomycin: zone size reported 16 (acceptable range 17-21) Enterococcus (ATCC 29212) Ampicillin: zone size reported 24 (acceptable range 17-22). Ciprofloxacin: zone size reported 17 (acceptable range 21-33); Levofloxacin: zone size reported 18 (19-22) g) Week of May 15-19, 2023: E. coli (ATCC 25922): Cephalosporin 3rd: zone size reported 34 (acceptable range 23-28); Ciprofloxacin: zone size reported 44 (acceptable range 30-40); Levofloxacin: zone size reported 44 (acceptable range 29-37); Nitrofurantoin: zone size reported 30 (acceptable range 20-25); Sulfa/TMP: zone size reported 32 (acceptable range 23-29); Tetracycline: zone size reported 30 (acceptable range 18-25); Cephalosporin 3rd (CRO30): zone size reported 40 (acceptable range 29-35), Gentamicin: zone size reported 28 (acceptable range 19-26); Imipinem {sic}: zone size reported 40 (acceptable range 26-32); Piperacillin: zone size reported 34 (acceptable range 24-20); Fosfomycin: zone size reported 36 (acceptable range 22-30) Enterococcus (ATCC 29212): Ampicillin: zone size reported 24 (acceptable range 17-22); Ciprofloxacin: zone size reported 17 (acceptable range 21-33); Levofloxacin: zone size reported 17 (acceptable range 19-22) h) Week of May 22-26, 2023: E. coli (ATCC 25922): Cephalosporin 1st: zone size reported 17 (acceptable range 15-21) S. aureus (ATCC 25923): Nitrofurantoin: zone size reported 17 (acceptable range 18-22) Enterococcus (ATCC 29212): Ampillicin: zone size reported 23 (acceptable range 17-22); Ciprofloxacin: zone size reported 16 (acceptable range 21-33); Levofloxacin: zone size reported 18 (acceptable 19-22) i) Week of May 29-June 2, 2023: Pseudomonas (ATCC 27853): Gentamicin:

	zone size reported 22 (acceptable range 16-21) E. coli (ATCC 25922): Levofloxacin: zone size reported 38 (acceptable range 29-37); Piperacillin: zone size reported 34 (acceptable range 24-30) S. aureus (ATCC 25923): Ciprofloxacin: zone size reported 33 (acceptable range 22-30); Levofloxacin: zone size reported 33 (acceptable range 25-30); Tetracycline: zone size reported 35 (acceptable range 24-30); Gentamicin: zone size reported 28 (acceptable range 19-27); Vancomycin: zone size reported 22 (acceptable range 17-21) Enterococcus(ATCC 29212): Ampicillcin: zone size reported 27 (acceptable range 17-22); Ciprofloxacin: zone size reported 19 (acceptable 21-33) j) Week of September 5-8, 2023: S. aureus (ATCC 25923): Ciprofloxacin: zone size reported 34 (acceptable range 22-30); Levofloxacin: zone size reported 34 (acceptable 25-30); Tetracycline: zone size reported 32 (acceptable range 24-30); Vancomycin: zone size reported 23 (acceptable range 17-21) Enterococcus (ATCC 29212): Ampicillin: zone size reported 29 (acceptable range 17-22); Ciprofloxacin: zone reported 20 (acceptable range 21-33) k) Week of September 11-15, 2023: E. coli (ATCC 25922): Cephalosporin 3rd: zone size reported 29 (acceptable range 23-28); Nitrofurantoin: zone size reported 26 (acceptable range 20-25); Tetracycline: zone size reported 26 (acceptable range 18-25); Cephalosporin 3rd (CRO30): zone size reported 36 (acceptable range 29-35) S. aureus (ATCC 25923): Ciprofloxacin: zone size reported 32 (acceptable range 22-30); Levofloxacin: zone size reported 33 (acceptable range 25-30) Enterococcus (ATCC 29212): Ampicillin: zone size reported 29 (acceptable range 17-22): Ciprofloxacin: zone size reported 18 (acceptable range 21-33) l) Week of September 18-22, 2023: Pseudomonas (ATCC 27853): Ciprofloxacin: zone size reported 34 (acceptable range 25-33) E. coli (ATCC 25922): Ampicillin: zone size reported 23 (acceptable ragne 16-22); Cephalosporin 3rd: zone size reported 31 (acceptable range 23-28); Ciprofloxacin: zone size reported 43 (acceptable range 30-40); Levofloxacin: zone size reported 42 (acceptable range 29-37); Nitrofurantoin: zone size reported 27 (acceptable range 20-25); Sulfa/TMP: zone size reported 30 (acceptable range 23-29); Tetracycline: zone size reported 28 (acceptable range 18-25); Cephalosporin 3rd (CRO30): zone size reported 37 (acceptable range 29-35) S. aureus (ATCC 25923): Levofloxacin: zone size reported 32 (acceptable range 25-30) Enterococcus (ATCC 29212): Ampicillin: zone size reported 27 (acceptable range 17-22); Ciprofloxacin: zone size reported 19 (acceptable range 21-33); Levofloxacin: zone size reported 18 (acceptable range 19-22) m) Week of September 25-29, 2023: S. aureus (ATCC 25923): Nitrofurantoin: zone size reported 17 (acceptable range 18-22) Enterococcus (ATCC 29212): Ampicillin: zone size reported 24 (acceptable range 17-22); Ciprofloxacin: zone size reported 16 (acceptable range 21-33); Levofloxacin: zone size reported 18 (acceptable range 19-22) 7. In interview on October 24, 2023 at 2:00 pm, Testing Personnel 1 stated the laboratory was aware the control zone for Enterococcus had been outside of the acceptable range limit and was monitoring. 8. In further interview on October 24, 2023 at 2:10 pm, the Technical Consultant confirmed no actions were taken for the identified microbiology quality control failures. 9. Review of the laboratory's test menu revealed the laboratory performs 1,311 antimicrobial susceptibility testing annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's policies, corrective action records, and interview with personnel, the laboratory failed to ensure assessment activities for performance of calibration for Chemistry testing were effective in correcting the issue identified. Findings: 1. Review of the laboratory's "Quality Assurance Manual" policy revealed "Documentation of periodic quality assurance review, including an assessment of problems identified and corrective action taken." 2. In interview on October 24, 2023 at 2:30 pm, the Technical Consultant stated the laboratory identified an issue of calibrations for the Chemistry analytes being performed late. The Technical Consultant stated the laboratory documented the findings on the "Corrective Action" forms. 3. Review of the laboratory's "Corrective Action" forms for the identified calibration issue revealed corrective actions to prevent recurrence were not documented and the issue continued to recur. The following incidents were documented: a) "AST, ALT, and ALKP were supposed to be calibrated on 7/18/22. A new lot was calibrated on 8/17/22. QC was with in range on all dates between 7/18 and 8/17. All laboratory personnel have been educated and updated regarding the above corrective action." The form was signed by the Technical Consultant on "8/17/22" and the Laboratory Director; however, no signatures by testing personnel. b) "TBIL was due for calibration on 8/9/22. New lot was calibrated on 8/22/22. QC was within range for all days patients were run between 8/9 and 8/22. All laboratory personnel have been educated and updated regarding the above corrective action." The form was signed by the Technical Consultant on "8/22/22" and the Laboratory Director; however, no signatures by testing personnel. c) "ALKP, AST, ALTV was calibrated on 3/14/23 was past due since 2/17/23. Quality Control was in range for all dates during this time. All laboratory personnel have been educated and updated regarding the above corrective action." The form was signed by the Technical Consultant on "3/14/23" and the Laboratory Director; however, no signatures by testing personnel. d) "Total Bilirubin was due for calibration on 2/22/23. The calibration was run on 3/14/23. QC was acceptable on dates between 2/22 and 3/14. All laboratory personnel have been educated and updated regarding the above corrective action." The form was signed by the Technical Consultant on "3/14/23" and the Laboratory Director; however, no signatures by testing personnel. e) "TBili was due for calibration on 9/14/23 and was run on 9/26/23. ALT, AST and ALKP was due on 9/14/23 but run on 9/25/23. Total Protein was due on 9/14/23 and run on 9/20/23. QC for all were in acceptable range for all dates in between when calibration was due and actually run." The form was signed by the Technical Consultant on "9/26/23" and the Laboratory Director; however, no signatures by testing personnel. 4. In interview on October 24, 2023 at 2:30 pm, the Technical Consultant confirmed the laboratory's quality assurance measures did not correct the calibration issue identified. II. Based on observation by surveyor, review of records, and interview with personnel the laboratory's quality assurance monitors failed to identify and correct issues within the analytic system. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies. Refer to D5403. 3. The laboratory failed to ensure the Complete Blood Count (CBC) procedures were approved and signed by the Laboratory Director. Refer to D5407. 4. The laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Refer to D5413. 5. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417. 6. The laboratory failed to have complete verification of performance specifications for Complete Blood Count (CBC) testing on the Medonic M series analyzer. Refer to D5421. 7. The laboratory failed to

	perform quality control checks weekly, per laboratory policy, to ensure the media's ability to support growth for two (2) of fourteen (14) weeks reviewed. Refer to D5477. 8. The laboratory failed to ensure quality control mean/range adjustments were documented for Chemistry testing. Refer to D5481. 9. The laboratory failed to ensure the sizes of control zones were within established limits for antimicrobial susceptibility testing for thirteen (13) of fourteen (14) weeks reviewed in 2023. Refer to D5507.
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 by surveyor, 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 verification 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 the laboratory documented complete corrective actions for unacceptable proficiency testing results. Refer to D6019. 4. The Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D6020. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 6. The Laboratory Director failed to ensure three (3) of six (6) Testing Personnel had complete training documentation prior to patient testing for the Medonic M Series analyzer utilized for Complete Blood Count (CBC) testing. Refer to D6029.
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 surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification 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 observation by surveyor, review of records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 2. The laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Refer to D5413. 3. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that 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 documented complete corrective actions for unacceptable proficiency testing results. Findings: 1. The laboratory failed to document assessment for unacceptable Routine Chemistry proficiency scores for one (1) out of five (5) events reviewed. Refer to D2094. 2. The laboratory failed to perform an assessment for unacceptable proficiency testing results for three (3) of five (5) proficiency testing (PT) events reviewed. Refer to D5221.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D5481.

D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793 I & II.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 personnel records and interview with personnel, the Laboratory Director failed to ensure three (3) of six (6) Testing Personnel had complete training documentation prior to patient testing for the Medonic M Series analyzer utilized for Complete Blood Count (CBC) testing. Findings: 1. Review of personnel records revealed the Technical Consultant (who also serves as Testing Personnel), Testing Personnel 1, and Testing Personnel 4 had training on the Medonic M Series; however, the Laboratory Director did not sign off on the training documents approving the personnel for patient testing. 2. In interview on October 24, 2023 at 11:44 am, the Technical Consultant confirmed the Laboratory Director did not sign the Medonic M Series training documents for the three (3) identified Testing Personnel.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(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 review of policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Findings: 1. The laboratory failed to establish complete policies and procedures to assess competency of laboratory personnel. Refer to D5209. 2. The Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included direct observation of performance of the test for two (2) of six (6) Testing Personnel reviewed. Refer to D6047. 3. The Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included review of test results, quality control records, proficiency testing results, and preventive maintenance records for two (2) of six (6) Testing Personnel reviewed. Refer to D6049.
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. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies. Refer to D5403. 3. The laboratory failed to ensure the Complete Blood Count (CBC) procedures were approved and signed by the Laboratory Director. 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 observation by surveyor, 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 established and maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included direct observation of performance of the test for two (2) of six (6) Testing Personnel reviewed. Refer to D6047. 5. The Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included review of test results, quality control records, proficiency testing results, and preventive maintenance records for two (2) of six (6) Testing Personnel reviewed. Refer to D6049.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, 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 ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 2. The laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Refer to D5413. 3. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.
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 observation by surveyor, record 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) 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 record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established and maintained to assure the quality of laboratory testing. Refer to D5481.

D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included direct observation of performance of the test for two (2) of six (6) Testing Personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory's 2023 competency assessments for the following personnel did not include documentation of direct observation of test performance: a) Testing Personnel 2: 2022: Hematology: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 2 on "9/8/22" and the Laboratory Director. 2023: Hematology: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 2 on "9/7/23" and the Laboratory Director. b) Testing Personnel 3: 2023: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 3 on "8/9/23" and the Laboratory Director. 2. In interview on October 24, 2023 at 11:24 am, the Technical Consultant confirmed the competency assessments for the identified personnel did not include documentation of direct observation of test performance.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to ensure 2022 and 2023 competency assessments for testing personnel performing moderate complexity testing included review of test results, quality control records, proficiency testing results, and preventive maintenance records for two (2) of six (6) Testing Personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory's 2023 competency assessments for the following personnel did not include documentation of review of test results, quality control records, proficiency testing results, and preventive maintenance records: a) Testing Personnel 2: 2022: Hematology: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 2 on "9/8/22" and the Laboratory Director. 2023: Hematology: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 2 on "9/7/23" and the Laboratory Director. b) Testing Personnel 3: 2023: Medonic M-Series, Immunochemistry-Beckman Coulter Access II, Chemistry-Vitros 350. Signed by Testing Personnel 3 on "8/9/23" and the Laboratory Director. 2. In interview on October 24, 2023 at 11:24 am, the Technical Consultant confirmed the

	competency assessments for the identified personnel did not include documentation of review of test results, quality control records, proficiency testing results, and preventive maintenance records.
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 surveyor, 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 the laboratory documented complete corrective actions for unacceptable proficiency testing results. Refer to D6092. 2. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 4. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Refer to D6103. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.
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. Refer to D5221.
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 perform quality control checks weekly, per laboratory policy, to ensure the media's ability to support growth for two (2) of fourteen (14) weeks reviewed. Refer to D5477. 2. The laboratory failed to ensure the sizes of control zones were within established limits for antimicrobial

	susceptibility testing for thirteen (13) of fourteen (14) weeks reviewed in 2023. Refer to D5507.
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 surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793 II.
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 policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Findings: 1. The laboratory failed to establish complete policies and procedures to assess competency of laboratory personnel. Refer to D5209. 2. The Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of internal blind, previously analyzed specimens, or external proficiency testing samples for one (1) of six (6) Testing Personnel reviewed. Refer to D6125. 3. The Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of problem solving skills for one (1) of six (6) Testing Personnel reviewed. Refer to D6126.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all

	personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies. Refer to D5403.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of Bacteriology testing. Refer to D6117. 2. The Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of internal blind, previously analyzed specimens, or external proficiency testing samples for one (1) of six (6) Testing Personnel reviewed. Refer to D6125. 3. The Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of problem solving skills for one (1) of six (6) Testing Personnel reviewed. Refer to D6126.
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 Bacteriology testing. Findings: 1. The laboratory failed to perform quality control checks weekly, per laboratory policy, to ensure the media's ability to support growth for two (2) of fourteen (14) weeks reviewed. Refer to D5477. 2. The laboratory failed to ensure the sizes of control zones were within established limits for antimicrobial susceptibility testing for thirteen (13) of fourteen (14) weeks reviewed in 2023. Refer to D5507.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of internal blind, previously analyzed specimens, or external proficiency testing samples for one (1) of six (6) Testing Personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory's 2023 competency assessments for the following personnel did not include documentation of assessment of internal blind, previously analyzed specimens, or external proficiency testing samples.: a) Testing Personnel 3: 2023: Microbiology: Signed by Testing Personnel 3 on "8/9/23" and the Laboratory Director. 2. In interview on October 24, 2023 at 11:24 am, the Technical Consultant confirmed the competency assessments for the identified personnel did not include documentation of assessment of internal blind, previously analyzed specimens, or external proficiency testing samples.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Supervisor failed to ensure the 2023 competency assessments for testing personnel performing high complexity testing included documentation of assessment of problem solving skills for one (1) of six (6) Testing Personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory's 2023 competency assessments for the following personnel did not include assessment of problem solving skills: a) Testing Personnel 3: 2023: Microbiology: Signed by Testing Personnel 3 on "8/9/23" and the Laboratory Director. 2. In interview on October 24, 2023 at 11:24 am, the Technical Consultant confirmed the competency assessments for the identified personnel did not include documentation of assessment of problem solving skills.