Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0710168	10/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Medical Clinical Laboratory	6569 Hwy 84, Ferriday, 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 Recertification survey was performed at Trinity Medical Center Laboratory, CLIA # 19D0710168, on October 23, 2023 through October 27, 2023. Trinity Medical Center Laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1201: CONDITION: Bacteriology 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 493.1459: CONDITION: Laboratories Performing High Complexity Testing; General Supervisor
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and bacteriology records, as well as interview with personnel, the laboratory failed to ensure quality laboratory services for the subspecialty of Bacteriology. Findings: 1. The laboratory failed to follow their policy for reporting urine culture colony count for three (3) of eight (8) patient test records reviewed. Refer to D5401 I. 2. The laboratory failed to perform gram stain quality control daily as required by the laboratory for six (6) of eight (8) days reviewed. Refer to D5401 II. 3. The laboratory failed to maintain complete policies and procedures for Microbiology. Refer to D5403. 4. The laboratory failed to have complete performance verification studies for the Vitek 2 analyzer. Refer to D5421 I. 5. The laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Refer to D5421 II. 6. The laboratory failed to verify performance specifications for microbiology media. Refer to D5421 III. 7. The laboratory failed to verify the organism colony count was included on the patient final

	report for positive urine cultures. Refer to D5421 IV. 8. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Microbiology susceptibility testing on the Vitek 2 analyzer. Refer to D5445.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS Laboratory Personnel Report (CMS-209), personnel records and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the General Supervisor were complete. Findings: 1. In interview on October 25, 2023 at 9:00 am, General Supervisor 2 stated that she wanted to update the CMS-209 form to include testing personnel 3 as General Supervisor for the specialty of Bacteriology. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a policy to assess the competency for the General Supervisor position and the frequency at which the competency is performed. 3. Review of the Laboratory Personnel Report (CMS-209) form revealed the laboratory identified Personnel 3 serves as General Supervisor. 4. Review of the personnel records for Personnel 3 in 2023 revealed that a competency assessment was not performed for the General Supervisory position. 5. In interview on October 25, 2023 at 9:00 am, General Supervisor 2 stated that Personnel 3 recently stepped in to the supervisory position with the addition of the specialty of Bacteriology. General Supervisor 2 confirmed the laboratory did not have a competency assessment policy or perform assessment for the Personnel 3 for the General Supervisor position.
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: I. Based on review of the laboratory's procedure manual and patient test records as well as interview with laboratory personnel, the laboratory failed to follow their policy for reporting urine culture colony count for three (3) of eight (8) patient test records reviewed. Findings: 1. Review of the laboratory's "Urine Culture Procedure" revealed ">24 hours: Report positive pathogens as X amount in K CFU/ml." 2. Review of patient test records revealed laboratory testing personnel did not document the positive urine culture colony count on the "Micro Flow Sheet" or in the Laboratory Information system (LIS) for the following specimens: - September 17, 2023 - Specimen number 75140 - September 29, 2023 - Specimen number 80567 3. In interview on October 25, 2023 at 3:45 pm, the Laboratory Manager confirmed that testing personnel did not document the colony count for the specimens identified

	above. II. Based on observation, review of patient test records and quality control records, as well as interview with personnel, the laboratory failed to perform gram stain quality control daily as required by the laboratory for six (6) of eight (8) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2023 at 1:39 p.m. revealed "When to QC" signage in the microbiology department which stated "Gram Stain - Each Day of Use." 2. Further observation by surveyors during the laboratory tour revealed a "Gram Slide" box with hand written instructions stating "QC Gran Stain - Each day of use *Record in yellow binder." 3. In interview on October 23, 2023 at 1:50 p.m., General Supervisor 1 stated gram stain quality control is performed each day of patient testing. 4. Review of patient test records revealed the laboratory did not document gram stain quality control on the "Gram Stain QC Log" on the following days with positive blood culture bottles: - August 13, 2023 - Patient 10325831 - August 15, 2023 - Patient 10325828 - August 19, 2023 - Patient 10326616 - August 22, 2023 - Patient 10326797 - September 13, 2023 - Patient 1032859 - September 17, 2023 - Patient 1032949 5. In interview on October 24, 2023 at 4:20 p.m., General Supervisor 1 confirmed gram stain quality control was not documented on the quality control log on the date identified above. 39352 III. Based on review of the laboratory's policy and procedures, blood bank quality control logsheet and interview with personnel, the laboratory failed to establish complete policies for blood bank. Findings: 1. Review of the blood bank policy manual revealed the laboratory did not have written policies that included the following: a) Blood Bank: written instructions for performance of freezer alarm check quarterly b) Blood Bank: written instructions for documenting the expiration dates for saline 2. In interview on October 25, 2023 at 3:12 pm, General Supervisor 2 stated that an aliquot is poured from the blood bank saline bottle and that the aliquot is utilized for one month (30 days). General Supervisor 1 further stated that personnel documents the monthly expiration date on the aliquot bottle and on the quality control logsheet. 3. Review of the laboratory's blood bank quality control logsheets revealed the laboratory did not document the saline expiration date as per the verbal policy for the following days: a) September 8, 2023 - Lot 2316512 Expiration 12/06/2024 (last documentation of monthly saline expiration on September 1, 2023) b) September 11, 2023 - Lot 2316512 Expiration 12/06/2024 (last documentation of monthly saline expiration on September 1, 2023) c) September 13, 2023 - Lot 2316512 Expiration 12 /06/2024 (last documentation of monthly saline expiration on September 1, 2023) d) September 14, 2023 - Lot 2316512 Expiration 12/06/2024 (last documentation of monthly saline expiration on September 1, 2023) e) September 18, 2023 - Lot 2316512 Expiration 12/06/2024 (last documentation of monthly saline expiration on September 1, 2023) f) September 19, 2023 - Lot 2316512 Expiration 12/06/2024 (last documentation of monthly saline expiration on September 1, 2023) 4. In interview on October 25, 2023 at 3:12 pm, General Supervisor 2 confirmed that laboratory personnel did not document the saline expiration date as required by policy for the above identified dates.
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: II. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy for method comparison testing. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include the following: a) Written instructions for method comparison studies, to include but not limited to, methodology and instrumentation utilized, frequency of performance, acceptibility criteria, review and approval documentation, retention of records... 2. In interview on October 26, 2023 at 5:30 pm, General Supervisor 2 confirmed the laboratory did not have a method comparison policy included in policy manual. 47757 I. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain complete policies and procedures for Microbiology. Findings: 1. Review of all laboratory policy and procedure manuals revealed the laboratory did not include complete policies and procedures for Microbiology including but not limited to: a) Microscopic examination, including the detection of inadequately prepared gram stain slides. b) Quality Control procedures: - To check each batch of media for sterility - To check that each batch/shipment of media supports growth and what organisms to utilize - To check each batch/shipment of media for its ability to select or inhibit specific organisms or produce a biochemical response and what organisms to utilize - To check each batch/shipment of biochemical tests to include but not limited to cefinase, hippurate, optochin, catalase, staphaurex, and PYR disk - Acceptability criteria for all aspects of Microbiology Quality Control. c) Step-by-step performance of all specimen culture procedures and interpretation of results to include: - Pathogens - Normal flora - Maximum number of colony types - Mixed flora - Biochemical tests - Quantitation if applicable d) Current media utilized by laboratory - CNA and Modified Thayer Martin included in laboratory media policy, but not utilized by the laboratory e) All critical values defined: - Policy stated the following: "Positive blood cultures, Positive Gram Stain and Culture, Streptococcus pyogenes (group A Streptococcus) in a surgical wound, Gram stain suggestive of gas gangrene (large box shaped gram positive rods), Detection of a significant pathogen (e.g., Legionella, Brussels, vancomycin-resistant Staphylococcus aureus)." 2. In interview on October 26, 2023 at 5:30 p.m., the Laboratory Manager confirmed the laboratory policies did not have complete information as identified above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, manufacturer's instrument manual, quality control records, and patient test records, as well as interview with personnel, the laboratory failed to ensure the Rapid Plasma Reagin (RPR) antigen met the temperature requirements of the manufacturer for one (1) of one hundred fourteen (114) patients reviewed. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs RPR testing utilizing the BD Macro-Vue RPR kit. 2. Review of the manufacturer's package insert revealed "Immediate use of a refrigerated antigen may result in decreased sensitivity of the test. Therefore, upon removal from the refrigerator, allow the antigen to warm to room temperature (23 to 29 degrees Celsius) before use." 3. Review of the laboratory's RPR logs from April 2023 through September 2023 revealed the room temperature was documented as outside of the manufacturer's acceptable range on 04/16/2023 with one (1) patient tested: - 21.5 degrees Celsius - patient 10314498 4. In interview on October 26, 2023 at 4:30 p.m., the Laboratory Manager confirmed the temperature was outside of the manufacturer's acceptable range as identified above.
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, review of the laboratory's temperature records and policy and procedure manual, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for blood gas testing supplies stored in the respiratory laboratory. Findings: 1. Observation by surveyors during the laboratory tour on October 24, 2023 at 10:18 a. m. revealed the laboratory stored the following blood gas testing supplies at room temperature in the respiratory laboratory: - GEM Calibration Valuation Product (CVP) 1 - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 1848; Expiration date: September 30, 2024; Quantity: One (1) box - GEM Calibration Valuation Product (CVP) 2 - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 2848; Expiration date: September 30, 2024; Quantity: One (1) box - GEM Calibration Validation Product (CVP) Multipak - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 849; Expiration date: June 30, 2025; Quantity: One (1) box - GEM 3500 Sensor Reagent and Cartridge - Manufacturer's storage requirements 15-25 degrees Celsius; Lot 322335J; Expiration date: February 7, 2024; Quantity: One (1) box - GEM 3500 Sensor Reagent and Cartridge - Manufacturer's storage requirements 15-25 degrees Celsius; Lot 327235D; Expiration date: March 27, 2024; Quantity: One (1) box - GEM 3500 Sensor Reagent and Cartridge - Manufacturer's storage requirements 15-25 degrees Celsius; Lot 322735C; Expiration date: February 11, 2024; Quantity: One (1) box 2. Review of the laboratory's temperature logs from March 2022 through September 2023 revealed the

	laboratory defined the room temperature acceptable limits as 15-32 degrees Celsius which exceeded the manufacturer's acceptable lower and upper limit for the following supplies: - GEM Calibration Valuation Product (CVP) 1 - GEM Calibration Valuation Product (CVP) 2 - GEM Calibration Validation Product (CVP) Multipak 3. Further review of the laboratory's temperature logs from March 2022 through September 2023 revealed the laboratory's acceptable limits for room temperature of 15-32 degrees Celsius exceeded the manufacturer's acceptable upper limit for the GEM 3500 Sensor Reagent and Cartridge 4. In interview on October 24, 2023 at 10:31 a.m., Respiratory Testing Personnel 1 confirmed the room temperature limits defined by the laboratory exceeded the manufacturer's acceptable storage limits as identified above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's package inserts, and interview with personnel, the laboratory failed to document the receipt and expiration date for blood gas testing supplies as required. Findings: 1. Observation by surveyors during the laboratory tour on October 24, 2023 at 10:18 a.m. revealed the laboratory stored the following blood gas testing supplies at room temperature in the respiratory laboratory: - GEM Calibration Valuation Product (CVP) 1 - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 1848; Expiration date: September 30, 2024; Quantity: One (1) box - GEM Calibration Valuation Product (CVP) 2 - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 2848; Expiration date: September 30, 2024; Quantity: One (1) box - GEM Calibration Validation Product (CVP) Multipak - Manufacturer's storage requirements 20-28 degrees Celsius; Lot 849; Expiration date: June 30, 2025; Quantity: One (1) box 2. Review of the manufacturer's package inserts for the items listed above revealed "Unopened ampules are stable until the expiration date shown on the label when stored at 2-8 degrees Celsius, or up to 12 months at room temperature (20-28 degrees Celsius), providing storage does not exceed the expiration date." 3. Further observation by surveyors revealed the supplies identified above did not have the date the laboratory began storage of the items at room temperature and did not have an updated expiration date. 4. In interview on October 24, 2023 at 10:31 a.m., Respiratory Testing Personnel 1 confirmed the items identified above did not have an room temperature storage start date and updated expiration date.
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: I. Based on observation by surveyor, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for the Vitek 2 analyzer. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2013 at 1:39 p.m. revealed the laboratory utilized the bioMerieux Vitek 2 analyzer for bacterial identification and susceptibility testing. 2. Review of the laboratory's validation records for the Vitek 2 revealed the laboratory included only raw data and did not include a validation plan for the Vitek 2 analyzer and/or review of the following studies: a) Accuracy b) Complete Precision: to include day-to-day, run-to-run, operator variance 3. In interview October 25, 2023 at 2:56 p.m., the Laboratory Manager confirmed the laboratory did not include the above information in the validation data. II. Based on observation by surveyors, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2013 at 1:39 p.m. revealed the laboratory utilized the BacT/Alert analyzer for microbial detection in blood cultures. 2. Review of the validation records for the BacT/Alert analyzer revealed the laboratory had a policy "Blood Culture Validation Study" which was not signed by the Laboratory Director. 3. Further review of the laboratory's validation studies revealed the laboratory did not include the following: a) Accuracy - Three (3) out of twenty-three (23) bottles inoculated with an organism did not produce a positive result and were not evaluated for acceptability - No documentation of positive blood culture workup from bottle inoculation through identification to show positive bottles produced expected organism - Pediatric bottles were not spiked with normal blood to produce a negative result - Pediatric bottles were not inoculated with all organisms listed in study - Raw data of growth and no growth in bottles did not match results in blood culture chart documenting growth and no growth b) Precision (run to run, day to day, within run, operator variance) 4. In interview on October 25, 2023 at 12:04 p.m., the Laboratory Manager confirmed the laboratory did not have documentation of accuracy and precision as identified above. III. Based on observation, review of the laboratory's policy and procedure manual and validation records, as well as interview with personnel, the laboratory failed to verify performance specifications for microbiology media. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2023 at 1:39 p.m. revealed the laboratory utilized the following media for organism growth in Microbiology: Blood Agar Plates (BAP), MacConkey Agar (MAC), Chocolate Agar (CHOC), Thioglycollate, Todd Hewitt Broth, BacT/Alert FA Plus, BacT/Alert FN Plus, and BacT/Alert PF Plus. 2. Review of the laboratory's validation records revealed the laboratory did not perform verification studies for microbiology media listed above. 3. In interview on October 24, 2023 at 3:15 p.m., the Laboratory Manager confirmed the laboratory did not verify the performance specifications for the media identified above.
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, review of the laboratory's policies and logs, as well as interview with laboratory personnel, the laboratory failed to ensure maintenance was performed on the GEM 3500 analyzer as required by the laboratory for nineteen (19) of nineteen (19) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on October 24, 2023 at 10:18 a.m. revealed the laboratory utilized the GEM 3500 analyzer. 2. Review of the laboratory's "GEM 3500 Statement of Policy" revealed the following: - Wipe the outer surface of the case using a soft cloth moistened with a 50/50 mixture of liquid chlorine bleach and water. - Wipe the surface of the touch screen using a soft cloth moistened with water or a mild, non-bleach cleaning solution. - Inspect the area into which the cartridge inserts, and clean as necessary. - Periodically remove the QC ampule breaker storage container and empty contents into an appropriate container, QC solution stains may be removed using a mild cleaning solution. 3. Review of the laboratory's logs revealed the laboratory did not document performance of maintenance from March 2022 to September 2023. 4. In interview on October 24, 2023 at 10:17 a.m., Respiratory Testing Personnel 1 stated that maintenance is performed but not documented. She confirmed maintenance was not documented for the months identified above.
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, review of the laboratory's policy and procedure manual, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Microbiology susceptibility testing on the Vitek 2 analyzer. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2023 at 1:39 p.m. revealed the laboratory utilized the Vitek 2 analyzer for microbiology susceptibility testing. 2. Review of the laboratory's "IQCP for Commercial Antimicrobial Susceptibility Testing (AST) on the BioMerieux Vitek 2 System" revealed the following components were not included: a) Quality Control Plan to include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s) b) Quality Assessment Plan to monitor the reduction in quality control frequency. 3. In interview on October 25, 2023 at 2:56 p.m., the Laboratory Manager confirmed the laboratory's IQCP did not include a Quality Control Plan and Quality Assessment Plan.
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:
I. Based on observation by surveyor, review of manufacturer's package inserts, quality control (QC) records and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for Hemoglobin A1C testing. Findings: 1. Observation by surveyor during the laboratory tour on October 23, 2023 at 10:30 am revealed the laboratory utilizes the Beckman Coulter AU 480 and Beckman Coulter DXH 690T chemistry analyzers for Hemoglobin A1C testing with extendSURE controls. 2. Review of the manufacturer's package insert for extendSURE controls under "Value Assignment, Traceability Statement and Assay Values" section revealed "Since the assay values are dependent upon assay procedures as well as several other factors and because other assay systems may produce different values it is recommended that each laboratory should establish its own control limits form day-to-day use of the test." 3. Review of the laboratory's quality control (QC) records revealed the laboratory did not have documentation of establishing their own QC means and ranges. 4. In interview on October 26, 2023 at 5:30 pm, General Supervisor 2 stated that she does not handle the QC establishment for Hemoglobin A1C quality controls but she does not believe the laboratory establishes the means and ranges for this QC material. General Supervisor 2 confirmed the laboratory did not have documentation to support QC establishment for Hemoglobin A1C QC establishments. II. Based on observation by surveyor, review of laboratory policy, manufacturer's package inserts, quality control (QC) records and interview with personnel, the laboratory failed to establish their own means and ranges for QC materials utilized for chemistry testing. Findings: 1. Observation by surveyor during the laboratory tour on October 23, 2023 at 10:30 am revealed the laboratory utilizes the Beckman Coulter AU 480 and Beckman Coulter DXH 690T chemistry analyzers along with the BioRad Multiqual Chemistry Controls for the following tests: Acetaminophen (ACET), Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Ammonia (AMM), Amylase (AMY), Direct Bilirubin (DBIL), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (CA), Creatinine (CREA), Carbamazepine (CARB), Cholesterol (CHOL), Creatine Kinase (CK), Dilantin (DIL), Digoxin (DIG), Phenobarbital (PHENO), Alcohol (ETOH), Salicylate (SALI), Gentamicin (GENT), Vancomycin (VANC), Lactic Acid (LA), Phosphorus (PHOS), Total Protein (TP), High Density Lipoprotein (HDL), Lipase (LIP), Uric Acid (UA), Sodium (NA), Potassium (K+), Chloride (CL), Carbon Dioxide (CO2), Glucose (GLUC), Iron (FE), Magnesium (MG), Triglycerides (TRIG), Transferrin (TRANS), Total Iron Binding Capacity (TIBC) 2. Review of the "Laboratory General Policy Guidelines" for "Changing Lot Number of Controls" revealed "Perform at least 20 runs of each test for each level of control. A greater number of runs may improve statistics of the assay range. Run the new lot of material in parallel with the current lot. Test the control

	values over several days, using controls and reagents over the time period and conditions under which they would normally be used for patient testing. The controls that have been tested on fresh reagents and or from the same bottle of control can lead to very tight assay ranges". 3. Review of the manufacturer's package insert for BioRad Multiqual Chemistry controls under "Assignment of Values" revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided as guides". 4. Review of the laboratory's BioRad Multiqual quality control (QC) establishments revealed the laboratory did not have documentation to support the QC means and ranges currently in use for the following tests: Acetaminophen (ACET) Amylase (AMY) Total Bilirubin (TBIL) Blood Urea Nitrogen (BUN) Calcium (CA) Carbamazepine (CARB) Cholesterol (CHOL) Creatine Kinase (CK) Dilantin (DIL) Digoxin (DIG) Phenobarbital (PHENO) Gentamicin (GENT) Vancomycin (VANC) Phosphorus (PHOS) Total Protein (TP) High Density Lipoprotein (HDL) Lactic Acid (LA) Uric Acid (UA) Sodium (NA) Potassium (K) Chloride (CL) Carbon Dioxide (CO2) Iron (FE) Triglycerides (TRIG) Transferrin (TRANS) Total Iron Binding Capacity (TIBC) 5. In interview on October 26, 2023 at 5:30 pm, General Supervisor 2 stated that another personnel handles the QC establishments for Chemistry testing and that she could not find the documentation to support the establishments. General Supervisor 2 confirmed the laboratory did not have QC establishment documentation for the above identified chemistry tests.
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: Based on observation by surveyor, review of laboratory records and interview with personnel, the laboratory failed to perform method comparison testing for all chemistry analytes at least twice per year for one (1) of four (4) correlations reviewed in 2022 and 2023. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2023 at 10:30 am revealed the laboratory utlizes the Beckman Coulter AU480 and Beckman Coulter DXH 690T analyzers for the following chemistry test comparisons: Sodium (NA), Potassium (K+), Chloride (CHL), Carbon Dioxide (CO2), Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Glucose (GLUC), Blood Urea Nitrogen (BUN), Creatinine (CREA), Calcium (CA), Albumin (ALB), Total Protein (TP), Total Bilirubin (TBIL), Creatine Kinase (CK), Amylase (AMY), Lipase (LIP), Magnesium (MAG), Phosphorus (PHOS), Lactate (LA) 2. Review of the laboratory's chemistry method comparison records from 2022 and 2023 revealed the laboratory did not perform correlation testing for the following four (4) of twenty (20) chemistry analytes in December 2022: a) Carbon Dioxide (CO2) b) Calcium (CA) c) Lactate (LA) d) Magnesium (MG) 5. In interview on October 26, 2023 at 5:30 pm, General Supervisor 2 confirmed that the identified tests were not included for the twice per year chemistry method comparison testing in December 2022.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, review of quality control records and policies, and interview with laboratory personnel, the laboratory failed to document all corrective actions taken when coagulation quality control was outside the laboratory's acceptable limits for nine (9)of sixty-one (61) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on October 23, 2023 at 1:39 p.m. revealed the laboratory utilized the ACL Top 350 for the following coagulation tests: Prothrombin Time (PT), Activated Partial Thromboplastin Time (PTT), and D-Dimer (DDHS). 2. Review of laboratory policy "Coagulation Department" revealed the laboratory performs two levels of Werfen Instrumentation Lab quality control once every eight hours of patient testing. 3. Review of quality control records for January 2023 and September 2023 revealed the laboratory repeated quality control that was outside the laboratory's acceptable limits but did not document corrective action steps performed on the following dates: PT Normal Control 1 09/24/2023 at 16:35:07 09/25/2023 at 16:33:20 PT Abnormal Control 3 01/06/2023 at 02:02:12 01/06/2023 at 02:07:16 01/15/2023 at 01:15:43 01/26/2023 at 13:39:03 01/26/2023 at 13:44:26 01/26/2023 at 14:22:50 DDHS 500 Control Level 1 01/27/2023 at 00:36:39 09/16/2023 at 00:47:32 09/16 /2023 at 01:49:13 09/29/2023 at 16:35:20 DDHS 500 Control Level 2 01/22/2023 at 00:37:09 09/16/2023 at 00:47:15 09/16/2023 at 00:55:02 09/16/2023 at 01:06:59 09/16 /2023 at01:19:14 09/16/2023 at 01:49:30 4. In interview on October 26, 2023 at 4:30 p.m., the Laboratory Manager confirmed the quality control runs identified above did not have corrective action documented.
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: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to follow their policy for reporting urine culture colony count for three (3) of eight (8) patient test records reviewed. Refer to D5401 I. 2. The laboratory failed to perform gram stain quality control daily as required by the laboratory for six (6) of eight (8) days reviewed. Refer to D5401 II. 3. The laboratory failed to establish complete policies for blood bank. Refer to D5401 III. 4. The laboratory failed to maintain complete policies and procedures for Microbiology. Refer to D5403 I. 5. The laboratory failed to establish a complete

	policy for method comparison testing. Refer to D5403 II. 6. The laboratory failed to ensure the Rapid Plasma Reagin (RPR) antigen met the temperature requirements of the manufacturer for one (1) of one hundred fourteen (114) patients reviewed. Refer to D5411. 7. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for blood gas testing supplies stored in the respiratory laboratory. Refer to D5413. 8. The laboratory failed to document the receipt and expiration date for blood gas testing supplies as required. Refer to D5415. 9. The laboratory failed to have complete performance verification studies for the Vitek 2 analyzer. Refer to D5421 I. 10. The laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Refer to D5421 II. 11. The laboratory failed to verify performance specifications for microbiology media. Refer to D5421 III. 12. The laboratory failed to ensure maintenance was performed on the GEM 3500 analyzer as required by the laboratory for nineteen (19) of nineteen (19) months reviewed. Refer to D5429. 13. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Microbiology susceptibility testing on the Vitek 2 analyzer. Refer to D5445. 14. The laboratory failed to establish their own means and ranges for QC material utilized for Hemoglobin A1C testing. Refer to D5469 I. 15. The laboratory failed to establish their own means and ranges for QC materials utilized for chemistry testing. Refer to D5469 II. 16. The laboratory failed to perform method comparison testing for all chemistry analytes at least twice per year for one (1) of four (4) correlations reviewed in 2022 and 2023. 17. The laboratory failed to document all corrective actions taken when coagulation quality control was outside the laboratory's acceptable limits for nine (9)of sixty-one (61) days reviewed. Refer to D5783.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance verification studies, procedures, and patient test records, as well as interview with personnel, the laboratory failed to verify the organism colony count was included on the patient final report for positive urine cultures. Findings: 1. Review of validation records revealed final test reports for cultures including a urine culture identified as "#1." 2. Further review of culture "#1" revealed the colony count was not included in the final test report. 3. Review of the laboratory's "Urine Culture Procedure" revealed ">24 hours: Report positive pathogens as X amount in K CFU/ml." 4. Review of patient final reports for positive urine cultures revealed the colony count was not reported for the following patient specimens: 68399 75140 79756 79855 80130 80154 80173 80567 5. In interview on October 25, 2023 at 3:45 pm, the Laboratory Manager confirmed the laboratory did not verify the final report for positive urine cultures included the organism colony count.

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 the Rapid Plasma Reagin (RPR) antigen met the temperature requirements of the manufacturer for one (1) of one hundred fourteen (114) patients reviewed. Refer to D5411. 2. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for blood gas testing supplies stored in the respiratory laboratory. Refer to D5413. 3. The laboratory failed to document the receipt and expiration date for blood gas testing supplies as required. Refer to D5415. 4. The laboratory failed to perform method comparison testing for all chemistry analytes at least twice per year for one (1) of four (4) correlations reviewed in 2022 and 2023.
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 observation by surveyors, review of laboratory records, 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. Findings: 1. The laboratory failed to establish their own means and ranges for QC material utilized for Hemoglobin A1C testing. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for QC materials utilized for chemistry testing. Refer to D5469 II.
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 D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.
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 review of laboratory policies and interview with laboratory personnel, the

	Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403 II.
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 review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure the Rapid Plasma Reagin (RPR) antigen met the temperature requirements of the manufacturer for one (1) of one hundred fourteen (114) patients reviewed. Refer to D5411. 2. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for blood gas testing supplies stored in the respiratory laboratory. Refer to D5413. 3. The laboratory failed to document the receipt and expiration date for blood gas testing supplies as required. Refer to D5415. 4. The laboratory failed to ensure maintenance was performed on the GEM 3500 analyzer as required by the laboratory for nineteen (19) of nineteen (19) months reviewed. Refer to D5429. 5. The laboratory failed to perform method comparison testing for all chemistry analytes at least twice per year for one (1) of four (4) correlations reviewed in 2022 and 2023.
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. Findings: 1. The laboratory failed to establish their own means and ranges for QC material utilized for Hemoglobin A1C testing. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for QC materials utilized for chemistry testing. Refer to D5469 II.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
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 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 established to assure the quality of laboratory services provided. D6094. 4. Based on record review and interview with personnel, the Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D6098. 5. The Laboratory Director failed to ensure four (4) of seven (7) testing personnel had appropriate training documentation prior to patient testing in 2023. Refer to D6102 I. 6. The Laboratory Director failed to ensure one (1) of seven (7) testing personnel had a competency assessment performed for intial training in the specialty of Microbiology. Refer to D6102 II. 7. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6103. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.
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. Findings: 1. The laboratory failed to have complete performance verification studies for the Vitek 2 analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Refer to D5421 II. 3. The laboratory failed to verify performance specifications for microbiology media. Refer to D5421 III.
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. Refer to D5445.
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 D5793.
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 the patient test reports included pertinent information required for interpretation. Refer to D5805.
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: I. Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure four (4) of seven (7) testing personnel had appropriate training documentation prior to patient testing in 2023. Findings: 1. In interview on October 23, 2023 at 10:30 am, General Supervisor 1 stated that the laboratory started patient testing for the specialty of Microbiology in July 2023. 2. Review of the personnel records from 2023 revealed the laboratory director performed initial

	competency assessments for the following four (4) of seven (7) testing personnel in the specialty of Microbiology: a) Personnel 3 b) Personnel 4 c) Personnel 6 d) Personnel 8 3. Further review of personnel records revealed the laboratory director did not include documentation to support the training for the following competency elements for four (4) of seven (7) testing personnel: a) Urine Colony Counts b) BioChemical tests (to include but not all inclusive) - Cefinase, Hippurate, Optochin, Staphaurex, PYR Disk 4. In interview on October 25, 2023 at 930 am, General Supervisor 2 confirmed the documentation for above competency elements were not assessed for the identified testing personnel along with the Laboratory Director approval to perform patient testing. II. Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of seven (7) testing personnel had a competency assessment performed for intial training in the specialty of Microbiology. Refer to D6120 I.
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 D5209.
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 follow their policy for reporting urine culture colony count for three (3) of eight (8) patient test records reviewed. Refer to D5401 I. 2. The laboratory failed to perform gram stain quality control daily as required by the laboratory for six (6) of eight (8) days reviewed. Refer to D5401 II. 3. The laboratory failed to establish complete policies for blood bank. Refer to D5401 III. 4. The laboratory failed to maintain complete policies and procedures for Microbiology. 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 observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. Based on observation and interview with personnel, 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 that a quality control program was maintained to assure the quality of Microbiology testing. Refer to D6117. 4. The Technical Supervisor failed to assess the competency for one (1) of seven (7) testing personnel for the specialty of Microbiology. Refer to D6120 I. 5. The Technical Supervisor failed to have documentation of initial training/orientation for four (4) of seven (7) testing personnel for the specialty of Microbiology. Refer to D6120 II.
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 and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5801.
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. Findings: 1. The laboratory failed to have complete performance verification studies for the Vitek 2 analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Refer to D5421 II. 3. The laboratory failed to verify performance specifications for microbiology media. Refer to D5421 III.
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. Refer to D5445.
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: I. Based on review of personnel records and interview with personnel, the Technical Supervisor failed to assess the competency for one (1) of seven (7) testing personnel for the specialty of Microbiology. Findings: 1. In interview on October 23, 2023 at 10: 30 am, General Supervisor 1 stated the laboratory started patient testing for the specialty of Microbiology in July of 2023. 2. Review of personnel records in 2023 revealed the laboratory did not have documentation of a competency assessment performed in the specialty of Microbiology for Personnel 2. 3. In interview on October 25, 2023 at 9:00 am, General Supervisor 2 stated that Personnel 2 only performs gram stain and specimen processing in Microbiology. 4. In further interview on October 25, 2023 at 9:00 am, General Supervisor 2 confirmed that a competency assessment was not performed for the above identified testing personnel in specialty of Microbiology
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel, the General Supervisor failed to provide day to day supervision or oversight to ensure accurate and reliable patient test results. Findings: 1. The General Supervisor failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Refer to D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the

	laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the General Supervisor failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to follow their policy for reporting urine culture colony count for three (3) of eight (8) patient test records reviewed. Refer to D5401 I. 2. The laboratory failed to perform gram stain quality control daily as required by the laboratory for six (6) of eight (8) days reviewed. Refer to D5401 II. 3. The laboratory failed to establish complete policies for blood bank. Refer to D5401 III. 4. The laboratory failed to maintain complete policies and procedures for Microbiology. Refer to D5403. 5. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Microbiology susceptibility testing on the Vitek 2 analyzer. Refer to D5445.