| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 26D0446923 | 04/01/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Texas County Memorial Hospital | 1333 S Sam Houston Blvd, Houston, MO | |

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 |
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| **D0000** | An recertification survey was completed on April 1, 2024. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.1100 Condition: Facility Administration 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1441 Condition: Laboratory Director |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation of laboratory temperature logs and interview, the laboratory failed to ensure protection from biological hazards for laboratory and hospital personnel (Refer to D3011). |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory temperature logs and interview with the general supervisor (GS) #2, the laboratory failed to ensure protection from biological hazards for laboratory and hospital personnel. Findings: 1. Review of refrigerator temperature log for March 2023 and April 2023 stated "Cafeteria walk-in stored reagents when our fridge was down". 2. During interview GS #2 stated, "Yes, Vitros chemistry reagents were stored in fridge in the cafeteria." 3. Interview with GS #2 on March 26, 2024 at 1: 30 PM confirmed the laboratory failed to ensure protection from biohazardous materials for laboratory and hospital personnel. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory procedures, patient reports, patient charts, correlation studies, Vitros 5600 chemistry quality control (QC), laboratory package inserts, RPR QC and maintenance logs, observation of microbiology rooms, review of temperature and humidity logs, review of the BacT/Alert blood culture analyzer and the Vitek 2 Compact microbiology analyzer manufacturer's instructions, observation of the Ortho Diagnostics Vitros 5600 chemistry analyzer, review of the Vitros 5600 alarm log and manufacturer's guidelines, observation of laboratory refrigerators and freezers, review of the performance verification procedures, calibration records, review of individualized quality control plans (IQCP), ESR QC, iStat QC, Biofire QC, lack of BBL catalase and BBL oxidase reagent QC, review of agar plates and broth media, gram stain QC, antimicrobial susceptibility testing (AST) records, d-dimer QC, instrument comparisons, review of blood bank history and worksheet logs, Community Blood Center of the Ozarks immunohematology consultation reports, lack of corrective action documentation and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow established laboratory procedures (Refer to D5401); the laboratory failed to provide a procedure for reviewing patient history prior to performing blood bank testing and failed to include a step-by-step procedure for performing QC on the Vitros 5600 chemistry analyzer (Refer to D5403); the laboratory failed to follow manufacturer's instructions for syphilis serology parameters (Refer to D5411); the laboratory failed to document room temperature and humidity in the microbiology department and failed to follow manufacturer's instructions for acceptable temperature for the Vitros 5600 chemistry analyzer (Refer to D5413); the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to perform calibration verification procedures at least once every six months to verify the laboratory's reportable range for hepatitis and HIV testing (Refer to D5439); the laboratory failed to ensure that the IQCPs included appropriate risk assessments (Refer to D5445); the laboratory failed to include two controls materials of different concentrations each day of patient testing (Refer to |

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| | D5447); the laboratory failed to perform a positive and negative quality control for the GI panel, blood culture identification 2 panel, respiratory panel and RPR syphilis each day of patient testing (Refer to D5449); the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results (Refer to D5469); the laboratory failed to check each lot number of BBL catalase reagent and BBL oxidase reagent for positive and negative reactivity (Refer to D5471); the laboratory failed to check each shipment and lot of agar plates and broth media for sterility if sterility is required for testing, its ability to support growth and as appropriate, select or inhibit specific organisms, and physical characteristics of the media (Refer to D5477); the laboratory failed to perform gram stain QC weekly (Refer to D5503); the laboratory failed to use control organisms to check the procedure each day of patient testing on the Vitek analyzer (Refer to D5507); the laboratory failed to test one sample of control material each 8 hours of testing on the iStat (Refer to D5537); the laboratory failed to include two levels of control material each 8 hours of operation for d-dimer (Refer to D5545); the laboratory failed to document quality control (QC) in blood bank (Refer to D5551); the laboratory failed to evaluate and define the relationship between test results using different instruments two times a year (Refer to D5775); the laboratory failed to have a system to identify and assess patient test results that appear inconsistent (Refer to D5777); and the laboratory failed to take corrective action necessary to ensure accurate and reliable patient test results (Refer to D5783). |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of procedures, patient progress notes in the patient chart and interview with the general supervisor (GS) #1, personnel failed to follow the established procedure for blood transfusions. Findings: 1. Review of the procedure "Blood Transfusion: Whole Blood and Packed Cells" states "Patient Progress Notes: Document time blood transfusion was started and completed." 2. Review of patient progress notes in patient chart showed patient #7255623 received packed red blood cells on January 15, 2024. Unit #400017 was issued on January 15, 2024 at 16:41, review of patient progress notes showed no documented time of start of transfusion or time transfusion completed. Unit #400022 was issued on January 15, 2024 at 20:38, review of patient progress notes showed no documented time transfusion completed. 3. Interview with the general supervisor (GS) #1 on March 26, 2024 at 1:00 PM confirmed personnel failed to follow the established procedure for blood transfusion.<br>B. Based on review of laboratory policy, correlation studies, and interview with general supervisor (GS) #1, the laboratory failed to follow established laboratory procedure. Findings: 1. Review of the laboratory procedure "Correlation Studies" states "For numeric values, the results must match within 10%, with expectations documented and approved by the medical director. Exception - Troponin from the Triage Meter vs the Vitros - results will be acceptable if they fall within normal /abnormal ranges due to the sensitivity differences of the analyzers". 2. Review of the correlation study documentation showed no documentation of numerical 10% or normal/abnormal results on the results for the analytes: troponin, glucose, BUN, |

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| | sodium, creatinine, potassium, CO2, and Chloride. 3. Interview with the GS #1 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to follow established laboratory procedure. 47802 |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of Vitros 5600 procedure, review of Vitros 5600 chemistry quality control (QC), patient results and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to include a step-by-step procedure for performing quality control (QC) on the Vitros 5600 chemistry analyzer. Findings: 1. Review of Vitros 5600 chemistry procedure showed no step-by-step procedure for performing quality control (QC) on the Vitros 5600 chemistry analyzer. 2. The laboratory performs approximately 219,152 chemistry tests per year. 3. Interview with the general supervisor (GS) #1 and GS #2 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to establish a step-by-step procedure performing quality control (QC) on the Vitros chemistry analyzer. 44735 B. Based on interview, review of blood bank procedures and interview with the general supervisor (GS) #1, the laboratory failed to provide a procedure for reviewing patient history prior to performing blood bank testing. Findings: 1. Interview with the GS #1 stated before blood bank testing is performed "patient history is checked by reviewing patient file cards and looking in CPSI." 2. Review of blood bank procedures showed no procedure for reviewing patient history prior to performing testing. 3. Interview with the GS #1 on March 26, 2024 at 12:30 PM confirmed the laboratory failed to provide a procedure for reviewing patient history prior to performing testing. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the SureVue RPR package insert, "RPR QC/Maint" Logs for 2022 /2023 and to date March 26, 2024, patient results, and interview with the general supervisor (GS) #2, the laboratory failed to follow manufacturer's instructions for syphilis serology parameters for 119 out of 142 days of patient testing. Findings: 1. Review of the SureVue RPR package insert states the following: "In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed"; "The needle should deliver 60 +/- 2 drops of antigen per milliliter when held in a vertical position"; "Mechanical rotator set at 100  5 rpm and circumscribing inch diameter, with humidity cover"; "Rotate at 100  5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds)." 2. Review of the "RPR QC/Maint" logs from August 2022 to date March 26, 2024 showed the laboratory failed to perform check for needle delivery, rotor rate per minute (RPM), circumscribe, and timer with each day of patient testing RPR specimens. 3. Interview with GS #2 on March 26, 2024 at 12:00 PM, confirmed the laboratory failed to follow manufacturer's instructions for syphilis serology parameters each day of patient testing. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on observation of two microbiology rooms, lack of room temperature logs, lack of humidity logs, review of the BacT/Alert blood culture analyzer manufacturer's instructions, review of the Vitek 2 Compact microbiology analyzer manufacturer's instructions, and interview with the general supervisor (GS) #1 and #2, the laboratory failed to document room temperature and humidity in the microbiology department. Findings: 1. Observation of microbiology room #1 in which the BacT/Alert blood culture analyzer is located showed no documentation for room temperature or humidity from January 2022 to date March 26, 2024. 2. Review of manufacturer's instructions for the BacT/Alert states "operating: 10-30 degrees Celsius. Operating humidity range 10% to 90% relative humidity." 3. Observation of microbiology room #2 in which the Vitek 2 Compact microbiology analyzer is located showed no documentation for room temperature or humidity from August 2022 to date March 26, 2024. 4. Review of manufacturer's instructions for the Vitek 2 Compact analyzer states "Operating Ambient Temperature Range: 15 degrees Celsius to 30 degrees Celsius. Operating Humidity Range: 20% to 80% relative humidity, non condensing.". 5. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:00 PM confirmed the laboratory failed to document room temperature and humidity in the microbiology department. 47802 B. Based on observation of the Ortho Diagnostics Vitros 5600 chemistry analyzer during laboratory tour, review of the Vitros 5600 alarm log, Vitros 5600 manufacturer's guidelines, ambient temperature logs and interview with the general supervisor (GS) #2, the laboratory failed to follow manufacturer's instructions |

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| | for acceptable temperature for the Vitros 5600 chemistry analyzer. Findings: 1. Observation of the Ortho Diagnostics Vitros 5600 chemistry analyzer's alarm log showed that the analyzer had 229 out of 504 alarms that showed the analyzer had an alarm for ambient temperature as 'high range" on the transient attention action malfunction log from March 23, 2024 at 10:07 AM to March 26, 2024 at 10:07 AM. 2. Review of the manufacturer's instructions for the Vitros 5600 states operating temperature is "15-30 degrees C". 3. The laboratory could not provide operator's guide for troubleshooting temperature alarms. 4. Review of the laboratory's ambient room temperature logs from 2023 to date March 26, 2024 showed the ambient room temperature was unacceptable for 6 of 451 days. 5. Interview with the GS #2 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to follow manufacturer's instruction for acceptable temperature for Vitros 5600 chemistry analyzer. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on observation of the blood bank freezer, and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to ensure laboratory quality control (QC), and calibrators were not used when they had exceeded their expiration date. Findings: 1. Observation of the blood bank freezer showed the following still in use: -1 box Sars-CoV2 Ag controls lot #1024 expiration 2/22/24 -1 box Sars-CoV2 Ag calibrator lot #1300 expiration 2/13/24 -1 box triage total 5 calibrators lot #487928N expiration 1/27/24 2. Interview with the GS #1 and the GS #2 on March 26, 2024 at 11:00 AM confirmed the laboratory failed to ensure laboratory QC and calibrators were not used when they had exceeded their expiration date. 47802 B. Based on observation of refrigerators during the laboratory tour and interview with the general supervisor (GS) #1, the laboratory failed to ensure that laboratory reagents were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory refrigerators during the laboratory tour showed one box of Vitros Gentamicin reagent, lot 16-9762 expiration date 03/14/2024 and one box Vitros A1C performance verifier, lot number V9428 expiration date 12/10/2023, still in use. 2. Interview with the GS #1 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>A. Based on review of the performance verification procedures for the ACL Top 350 coagulation analyzer, patient results and interview with the general supervisor (GS) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the ACL Top 350 coagulation analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: prothrombin time (PT), partial thromboplastin time (PTT), d-dimer, and fibrinogen prior to the beginning of patient testing in August 2023. 2. Review of patient results from August 2023 to date March 26, 2024 showed approximately 1604 prothrombin time (PT), approximately 1136 partial thromboplastin time (PTT), approximately 280 d-dimer and approximately 11 fibrinogen patient test results were reported. 3. Interview with the GS #1 on March 26, 2024 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results. 47802 B. Based on review of the performance verification procedures for the Ortho Diagnostics Vitros 5600 chemistry analyzer, miniiSED erythrocyte sedimentation rate (ESR) analyzer, patient results, and interview with the general supervisor (GS) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the Ortho Diagnostics Vitros 5600 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analyte creatine kinase MB (CK-MB) prior to the beginning of patient testing in December 2023 2. Review of patient test results for CK-MB from December 1, 2023 to date March 26, 2024 showed approximately 747 patient results were reported. 3. Review of the performance verification procedures for the Ortho Diagnostics Vitros 5600 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the N-terminal prohormone of brain natriuretic peptide (NT-pro-BNP) prior to the beginning of patient testing in November 2022. 4. Review of patient results for NT-pro-BNP from November 1, 2022 to date March 26, 2024 showed approximately 2832 patient results were reported. 5. Review of performance verification procedures for the miniiSED ESR analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analyte ESR prior to the beginning of patient testing in July 2023. 6. Review of patient results for ESR from July 2023 to day March 26, 2024 showed approximately 250 patient results were reported. 7. Interview with the GS #1 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following |

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| | occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2022, 2023, and to date March 26, 2024 calibration records for the Ortho Diagnostics Vitros 5600 chemistry analyzer and interview with the general supervisor (GS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Vitros 5600 calibration records for 2022, 2023, and to date March 26, 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: hepatitis B surface antigen, hepatitis B core antibody, hepatitis B confirm, hepatitis A IgM, hepatitis C, and human immunodeficiency virus (HIV). 2. Interview with the GS #2 on March 26, 2024 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for hepatitis and HIV testing. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of individualized quality control plans (IQCP) for the Osom heliobactor pylori kit test, Sure-Vue mononucleosis kit test, Illumigene clostridium difficile analyzer, triage analyzer, Sure-Vue serum human chorionic gonadotropin (hcg) kit test, blood culture media, and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to ensure that the IQCPs included appropriate risk assessments. Findings: 1. Review of IQCPs for Osom heliobactor pylori kit test, Sure-Vue mononucleosis kit test, Illumigene clostridium difficile analyzer, triage analyzer, Sure-Vue serum human chorionic gonadotropin (hcg) kit test, and blood culture media showed the laboratory's IQCPs needed a more in depth risk assessment that also include definitive quality control frequency. 2. Interview with the GS #1 and GS #2 |

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| | on March 26, 2024 at 2:00 PM confirmed the laboratory failed to ensure that IQCPs included appropriate risk assessments. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, miniiSED erythrocyte sedimentation rate (ESR) patient logs, miniiSED ESR analyzer quality control (QC), iStat analyzer QC, Vitros 5600 QC, patient results and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to include two controls materials of different concentrations each day of patient testing. Findings: 1. Review of miniiSED ESR procedure states "QC should be ran every day or within 24 hours of patient testing". 2. Review of miniiSED ESR QC showed no QC was performed on January 7, 2024, February 9, 2024 and February 25, 2024. 3. Review of miniiSED ESR patient logs showed four patients were resulted while QC was not performed. 4. Review of iStat analyzer chem8 cartridges showed that from January 2023 to date March 26, 2024 QC was not performed each day of patient testing for the analytes: hematocrit, glucose, blood urea nitrogen, sodium, chloride, potassium, ionized calcium, total carbon dioxide and creatinine. 5. The laboratory was unable to provide the volume of patient tests performed on iStat chem8 cartridge testing while QC was not performed. 6. Review of Vitros 5600 carbon dioxide for February 2024 QC showed that no QC was performed for carbon dioxide on February 4, 2024, February 5, 2024, February 6, 2024, February 7, 2024, and February 8, 2024. 7. The laboratory was unable to provide the volume of carbon dioxide patient tests performed while QC was not performed. 8. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:00 PM confirmed the laboratory failed to include two controls materials of different concentrations each day of patient testing for miniiSED ESR, iStat chem8 cartridges, and Vitros 5600 carbon dioxide testing. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the Biofire analyzer quality control (QC) for 2022, 2023 and to date March 26, 2024, review of patient results and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to perform a positive and negative quality control for the GI panel, blood culture identification 2 panel and the respiratory panel each day of patient testing. Findings: 1. Review of the Biofire |

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| | analyzer QC records showed the laboratory failed to perform a positive and negative quality control each day of patient testing for the GI panel, blood culture identification 2 panel and the respiratory panel from January 2022 to date March 26, 2024. 2. The laboratory performs approximately 7,187 microbiology tests per year. 3. Interview with the GS #1 and GS #2 on March 26, 2024 at 10:00 AM confirmed, the laboratory failed to perform a positive and negative quality control for the GI panel, blood culture identification 2 panel and the respiratory panel each day of patient testing. 47802 B. Based on review of the "RPR QC/Maint" logs, patient logs, and interview with the general supervisors (GS) #1 and #2, the laboratory failed to perform a positive and negative quality control for the RPR syphilis serology test each day of patient testing for 33 of 142 days of patient testing. Findings: 1. Review of the "RPR QC/Maint" and patient logs showed the laboratory failed to perform a positive and negative quality control each day of patient testing for the following days from August 1, 2022 to date March 26, 2024: 2022 August 3, August 9, September 12, October 10, October 17, October 20, and November 21 2023 January 16, February 21, February 23, March 7, March 16, March 22, April 25, May 11, June 12, June 22, June 29, July 18, August 17, August 20, September 18, October 17, October 31, November 6, November 29, and December 12 2024 January 7, January 9, January 22, January 29, February 27, and March 25 2. Review of patient logs showed 79 RPR syphilis patient tests were performed when the laboratory failed to perform quality control. 3. Interview with the GS #1 and GS #2 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to perform a positive and negative quality control for the RPR syphilis serology test each day of patient testing. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Vitros 5600 chemistry analyzer quality control (QC) records, review of 3 of 72 analytes on the Vitros 5600 chemistry analyzer, and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results. Findings: 1. Review of the Vitros 5600 QC records showed the laboratory used assayed Thermo Scientific MAS Omni CORE QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC when they had to change the ranges from the manufacturer's established ranges. 2. Review of Vitros 5600 analyzer showed total cholesterol QC range of 83.5-108.1 mg/dl. Thermo Scientific MAS Omni CORE manufacturer's package insert for total |

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| | cholesterol revealed an assayed value range of 83.5-104.1 mg/dl. The laboratory could not provide documentation for how total cholesterol QC range was established. 3. Interview with the GS #1 and GS #2 on March 26, 2024 at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of microbiology procedure, lack of BBL catalase reagent and BBL oxidase reagent quality control (QC), patient results and interview with general supervisor (GS) #1 and GS #2, the laboratory failed to check each lot number of BBL catalase reagent and BBL oxidase reagent for positive and negative reactivity.<br>Findings: 1. Review of "Quality Control Program for Microbiology" procedure states "Catalase document each shipment/lot received and perform QC per shipment/lot" and "Oxidase document each shipment/lot received and perform QC per shipment/lot". 2. Lack of microbiology QC showed no documentation of catalase and oxidase QC since patient testing started in August 2022. 3. Review of patients results showed the laboratory performs approximately 7,187 microbiology tests per year. 4. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:00 PM confirmed the laboratory failed to check each lot number of BBL catalase reagent and BBL oxidase reagent for positive and negative reactivity. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of agar plates, broth media, quality control (QC) documentation (logs) for microbiology, patient results, and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to check each shipment and lot of agar plates and broth media for sterility if sterility is required for testing, its ability to support growth and as appropriate, select or inhibit specific organisms, and physical characteristics of the media. Findings: 1. Review of agar plates showed blood agar plates, salmonella shigella (SS) agar plates, xylose lysine deoxycholate (XLD) agar |

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| | plates, V agar plates, columbia naladixicacid (CNA) agar plates, phenylethyl alcohol (PEA) agar plates, laked brucella blood (LKV) agar plates, anaerobe basal (ABA) agar plates, sabouraud (SAB) agar plates available to use with no documentation to show sterility if sterility is required for testing, no documentation to show ability to support growth and as appropriate, select or inhibit specific organisms, and no documentation of the physical characteristics of the media since patient testing started in August 2022. 2. Review of broth media showed LIM broth, selenite broth, thioglycolate (THIO) broth, and Todd Hewitt (TODD-HEW) broth available to use with no documentation to show sterility if sterility is required for testing, no documentation to show ability to support growth and as appropriate, select or inhibit specific organisms, and no documentation of the physical characteristics of the media since patient testing started in August 2022. 3. Review of chocolate agar plates revealed chocolate agar lot #791490 expiration April 5, 2024 in use. 4. Review of QC logs showed no documentation of chocolate agar plate lot #791490 for its ability to support growth. 5. Review of patients results showed the laboratory performs approximately 7,187 microbiology tests per year. 6. Interview with the GS #1 and #2 on March 26, 2024 at 11:00 AM confirmed the laboratory failed to check each shipment and lot of agar plates and broth media for sterility if sterility is required for testing, its ability to support growth and as appropriate, select or inhibit specific organisms, and physical characteristics of the media. |
| **D5503** | BACTERIOLOGY<br>CFR(s): 493.1261(a)(2)<br><br>(a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of gram stain quality control (QC), patient logs and interview with the general supervisor (GS) #1, the laboratory failed to perform gram stain QC weekly. Findings: 1. Review of gram stain QC showed no weekly QC performed for the following weeks from August 1, 2022 to date March 26, 2024: 2022 Week of November 27 Week of December 25 2023 Week of January 29 Week of April 9 Week of December 10 2024 Week of January 14 Week of January 21 2. Review of patient results showed the laborratory performed approximately 758 patients from August 1, 2022 to date March 26, 2024. 3. Interview with the GS #1 on March 26, 2024 at 12:00 PM confirmed the laboratory failed to perform gram stain QC weekly. |
| **D5507** | BACTERIOLOGY<br>CFR(s): 493.1261(b)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of antimicrobial susceptibility testing (AST) records for the Vitek 2 compact analyzer, patient results and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to use control organisms to check the procedure each day of patient testing. Findings: 1. Review of the AST records for the Vitek 2 compact analyzer which performs bacteria identification and susceptibility revealed the laboratory failed to use the appropriate control organisms for antimicrobial susceptibility on the Vitek 2 every day of patient testing. 2. Review of patients results showed the laboratory performs approximately 7,187 microbiology tests per year. 3. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:00 PM confirmed the laboratory failed to use control organisms for AST each day of patient testing. |
| **D5537** | ROUTINE CHEMISTRY<br>CFR(s): 493.1267(b)(d)<br><br>For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of iStat blood gas analyzer, review of iStat quality control (QC), patient results and interview with the general supervisor (GS) #3, the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. Findings: 1. Observation of the iStat blood gas analyzer showed the laboratory used the CG4+ cartridge. 2. Review of the iStat blood gas CG4+ QC showed no documentation of QC each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing from January 2023 to date March 26, 2024 for the analytes pH, pCO2, pO2 and lactate. 3. The laboratory was unable to provide the volume of patient tests performed on the iStat CG4+ cartridge testing while QC was not performed. 4. Interview with the GS #3 on March 26, 2024 at 11:30 AM confirmed the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. |
| **D5545** | HEMATOLOGY<br>CFR(s): 493.1269(b)(d)<br><br>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, ACL Top 350 coagulation analyzer quality control (QC), patient results and interview with the general supervisor (GS) #1, the laboratory failed to include two levels of control material each 8 hours of operation for d-dimer for 1 of 22 patient testing days in February 2024. Findings: 1. Review of laboratory procedure "Laboratory Quality Program" states "For all automated coagulation test systems, the laboratory must include two levels of control material each eight hours of operation and each time a reagent is changed." 2. Review of the |

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| | ACL Top 350 coagulation analyzer QC for February 2024 showed QC was not performed on February 27, 2024. 3. Review of patient results showed 2 patient d-dimer results were released when QC was not performed. 4. Interview with the GS #1 on March 26, 2024 at 10:30 AM confirmed the laboratory failed to perform two levels of d-dimer QC each 8 hours of operation. |
| **D5551** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(a)(f)<br><br>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the general supervisor (GS) #1, the laboratory failed to document quality control (QC) for one patient testing day from January 2023 to date March 26, 2024. Findings: 1. Review of the laboratory's blood bank procedure "Blood Bank Quality Control of Reagents" states "The potency and reliability of reagents that are used for ABO grouping, Rh typing, antibody detection and compatibility determinations must be tested on each date of use and when a new lot of reagents is first used." 2. Review of blood bank patient testing logs showed ABO grouping and Rh typing patient testing was performed on February 25, 2024. 3. Review of blood bank QC logs showed no documented QC on February 25, 2024. 4. Interview with the GS #1 on March 26, 2024 at 12:30 PM confirmed the laboratory failed to document quality control each day of patient testing. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of laboratory analyzers, review of instrument comparisons, and interview with the general supervisor (GS) #3, the laboratory failed to evaluate and define the relationship between test results using different instruments two times a year in 2023. Findings: 1. Observation of laboratory analyzers revealed an iStat analyzer and a Siemens Rapid Point 500e, both analyzers perform pH, pCO2, and PO2. 2. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and |

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| | the Siemens Rapid Point 500e analyzer twice a year in 2023. 3. Interview with the GS #3 on March 26, 2024 at 12:00 PM, confirmed the laboratory failed to evaluate and define the relationship between blood gas test results using different instruments two times a year in 2023 . |
| **D5777** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(b)(c)<br><br>(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's blood bank worksheet log, laboratory information system (LIS) blood bank history log, blood bank patient history file cards, Community Blood Center of the Ozarks immunohematology consultation reports and interview with the general supervisor (GS) #1, the laboratory failed to have a system to identify and assess patient test results that appear inconsistent. Findings: 1. Review of the laboratory's blood bank worksheet log showed patient #7255623 was transfused 3 units of packed red blood cells on January 15, 2024. 2. Review of the LIS blood bank history log showed patient #7255623 was transfused 1 unit of packed red blood cells on January 15, 2024. 3. Review of blood bank patient history file cards showed patient #7254411 on January 2, 2024 has "Anti-K and Anti-K". 4. Review of Community Blood Center of the Ozarks immunohematology consultation reports showed patient #7254411 on January 3, 2024 has "Anti- E and Anti-K." 5. Interview with the GS #1 on March 26, 2024 at 12:30 PM confirmed the laboratory failed to have a system to identify and assess patient test results that appear inconsistent. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, review of procedures, review of February 2024 Vitros 5600 quality control (QC) records for 6 of 72 analytes, lack of corrective action documentation and interview with the general supervisor (GS) #1 and GS #2, the laboratory failed to take corrective action necessary to ensure accurate and reliable patient test results when the Vitros 5600 QC was not within acceptable limits. Findings: 1. Interview with GS #2 stated "both Vitros chemistry controls must be in and if not, they perform a performance verifier that must be in". 2. Review of procedures revealed no procedure that stated performance verifiers should be performed when QC was not within acceptable limits. 3. Review of February 2024 |

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| | Vitros 5600 QC showed for lactic acid, acetaminophen, blood urea nitrogen, carbon dioxide, total iron binding capacity, and uric acid that performance verifiers were ran in place of or when QC was not within acceptable limits 47 times with no documentation and no corrective action. 4. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:00 PM confirmed the laboratory failed to take corrective action necessary to ensure accurate and reliable patient test results when the Vitros 5600 QC was not within acceptable limits. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on proficiency testing (PT) results, procedures, Illumigene quality control (QC), quality assessment program, Vitros 5600 QC, Sysmex XN-550 QC, and interviews, the laboratory director (LD)failed to provide overall management and direction of the laboratory. The LD failed to ensure PT testing reports were reviewed by the appropriate staff (Refer to D6091); the LD failed to ensure that QC was performed according to procedure (Refer to D6093); the LD failed to ensure quality assessment programs are established and maintained (Refer to D6094); the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the Vitros 5600 (Refer to D6095); and the LD failed to ensure laboratory personnel follow established laboratory procedure (Refer to D6106). |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the 2023 Microbiology proficiency testing (PT) records and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure all profiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's perfomance and to identify any problems that require corrective action. Findings: 1. Review of the 2023 Microbiology PT Event 1 records showed the laboratory obtained a not graded result for educational susceptability sample ES-01 and urine culture MIC/Zone sample UR-01. 2. Review of the 2023 Microbiology PT Event 3 records showed the laboratory obtained a not graded result for educational susceptability sample ES-03 and urine culture MIC/Zone sample UR-03 and unacceptable results for wound culture sample WO-02. 3. Interview with the GS #1 on March 26, 2024 at 12:00 PM confirmed the LD failed to ensure all proficiency testing reports recieved were reviewed by the appropriate staff to evaluate the laboratory's perfomance and to identify any problems that require corrective action. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of procedures, Illumigene clostridium difficile analyzer quality control (QC), patient numbers and interview with the general supervisor (GS) #1 and #2, the laboratory director (LD) failed to ensure that QC was performed according to procedure. Findings: 1. Review of Illumigene clostridium difficile analyzer procedure states "run a positive and negative control with each kit lot change and monthly". 2. Review of Illumigene clostridium difficile analyzer QC from September 2022 to date March 26, 2024 showed no QC was performed in May 2023, November 2023, and February 2024. 3. Review of patients results showed the laboratory performs approximately 7,187 microbiology tests per year. 4. Interview with GS #1 and GS #2 on March 26, 2024 at 12:15 PM confirmed the LD failed to ensure Illumigene clostridium difficile QC was performed according to procedure. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Review of laboratory procedures and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure quality assessment programs are established and maintained. Findings: 1. Review of the laboratory procedure "Laboratory Quality Program" states "The director shall ensure the following: Quality control and quality assurance programs are established." 2. Review of laboratory procedures showed no quality assurance programs were available for review for microbiology, hematology, chemistry or coagulation testing. 3. Interview with the GS #1 on March 26, 2024 at 1:30 PM confirmed the LD failed to ensure microbiology, hematology, chemistry and coagulation quality assurance programs are established and maintained. |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, review of February 2024 Vitros 5600 chemistry analyzer quality control (QC) for 6 of 72 analytes performed, patient results and interview with the general supervisor (GS) #1 and GS #2, the laboratory director (LD) failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the Vitros 5600. Findings: 1. Review of laboratory procedures showed "Laboratory Quality Program" addressed QC "for each non- |

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| | waived quantitative and qualitative procedure include two levels of control materials each day of testing". 2. Review of February 2024 Vitros 5600 chemistry analyzer quality control level 3 was not within acceptable limits for: TIBC on 2/17/24 uric acid on 2/1/24, 2/2/24 and 2/3/24 acetaminophen on 2/8/24, 2/10/24 and 2/24/24 blood urea nitrogen on 2/16/24 lactic on 2/6/24, 2/9/24, and 2/20/24 carbon dioxide on 2/3 /24, 2/10/24, 2/11/24, 2/16/24, 2/17/24 and 2/28/24 3. Review of February 2024 Vitros 5600 chemistry analyzer quality control level 1 was not within acceptable limits for: TIBC on 2/13/24, and 2/17/24 blood urea nitrogen on 2/8/24, and 2/20/24 4. Review of patients results showed the laboratory performs approximately 219,152 chemistry tests per year. 5. Interview with the GS #1 and GS #2 on March 26, 2024 at 2:30 PM confirmed the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the Vitros 5600 chemistry analyzer. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, Sysmex XN-550 hematology analyzer quality control (QC), patient results and interview with the general supervisor (GS) #2, the laboratory director (LD) failed to ensure laboratory personnel follow established laboratory procedure in 2022, 2023 and to date March 26, 2024. Findings: 1. Review of the laboratory procedure "Laboratory Quality Program" states "Automated hematology instruments require minimum two levels of control materials each day but the TCMH Laboratory will continue to run two levels approximately every 8 hours." 2. Review of the Sysmex XN-550 hematology analyzer QC showed the laboratory failed to follow the established procedure for running two levels of hematology QC every 8 hours in 2022, 2023 and to date March 26, 2024. 3. Review of laboratory patient results showed the laboratory performs approximately 159,140 hematology patient tests per year. 4. Interview with the GS #2 confirmed the laboratory director (LD) failed to ensure laboratory personnel follow established laboratory procedure. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the performance verification procedures for the Vitek 2 compact microbiology analyzer, review of training and competency documents and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to identify and document initial training needs for one of four testing personnel (TP) performing microbiology testing. Findings: 1. Review of the performance verification procedures |

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| | for the Vitek 2 compact microbiology analyzer showed the laboratory began patient testing in August 2022. 2. Review of training and competency documents showed the laboratory could not provide documentation for initial training and competency for TP #2 for the Vitek 2 compact microbiology analyzer. 3. Interview with the general supervisor #1 on March 26, 2024 at 2:00 PM, confirmed the technical supervisor failed to identify and document training needs for one TP performing testing on the Vitek 2 compact microbiology analyzer. |