| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0675381 | 05/17/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pittsburg Hospital, Llc | 2701 Us Hwy 271 North, Pittsburg, TX | |

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 onsite survey conducted May 16th and May 17th, 2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| **D2128** | HEMATOLOGY<br>CFR(s): 493.851(e)<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing records, corrective action checklist, and confirmed in interview the laboratory failed to include remedial action on patients tested on the day of proficiency testing failures for 1 of 1 coagulation events reviewed in 2022. The findings include: 1. Review of the American Proficiency Institute (API) 2022 Hematology / Coagulation - 1st Event result sheet had an unacceptable result for APTT coagulation testing for COA-02 and COA-03. Sample - Lab Result - [Expected Result] COA-02: 60 - [40-55] COA-03: 41 - [45-62] 2. Review of the laboratory "API Corrective Action Checklist" completed by the laboratory on 5/3/2022 did not address the question "Could patient results have been affected? If so, explain course of action:" 3. Surveyor queried on 5/16/2022 at 13:10 hours, in the conference room, general supervisor (GS) 1 for documentation that patients were assessed on the day of the failure as part of their remedial action, and none was provided. 4. In an interview on 5/16/2022 at 13:15 hours, in the conference room, GS1 confirmed that patients were not assessed, as part of the remedial action, for the coagulation PTT proficiency testing failure for the 1st event of 2022. |

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| **D3025** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(d)<br><br>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy, patient transfusion records from 2021 and 2022, and confirmed in interview, the facility failed to follow its policy to identify and investigate blood transfusion reactionss for six of ten patients reviewed. A) vitals B) hypotension C) pulse rate Findings included: 1. Review of the laboratory policy Blood and Blood Products Administration (Policy 31337.2) under Administration revealed "vital signs will be taken and recorded on the blood product ID tag and in EMR." A) Vitals 2. Random review of the transfusion records from 2021 to 2022 revealed insufficient documentation of the vitals on the blood product ID tag per the laboratory policy for three of ten transfusion records reviewed. Patient ID 030985 (2/1/2022) Unit W035221446651, exp 2/24/2022 Unit W035221437207, exp 2/24/2022 No vitals on blood product ID tag Patient ID 32947 (6/25/2021) Unit W035221227564, exp 7/20 /2021 No vitals at 15 minutes or post transfusion on blood product ID tag Patient ID 119919 (2/25/2022) Unit W035222121564, exp 3/25/2022 No pulse or respiratory post transfusion 3. Review of the laboratory policy Transfusion Reaction Investigation under Hemolytic and Febrile Reactions revealed "acute hemolytic reactions are the most severe adverse effects of transfusion known. Febrile, non-hemolytic reactions due to antibodies against HLA or white blood cell related antigens are commonly seen and range in severity from very mild to very severe. Both type of reactions may present similar initial symptoms, including...hypotension" B) Hypotension 4. Random review of the transfusion records from 2021 and 2022 revealed two of ten transfusion records of low blood pressure (hypotension) with a systolic change of greater than 30 mmHg without documentation of the nurse and/or physician accounting for the change. Patient ID 173681 (1/23/2022) Unit W035221391627, exp 2/11/2022 pre transfusion BP: 156/94 mmHg 15 minute BP: 116/81 mmHg Patient ID 98583 (6/28 /2021) Unit W035221253795, exp 7/22/21 1 hour BP: 194/90 complete BP: 146/70 C) Pulse Rate 5. Review of the laboratory policy Transfusion Reaction Investigation under Hemolytic and Febrile Reactions revealed "acute hemolytic reactions are the most severe adverse effects of transfusion known. Febrile, non-hemolytic reactions due to antibodies against HLA or white blood cell related antigens are commonly seen and range in severity from very mild to very severe. Both type of reactions may present similar initial symptoms, including...increased pulse rate" 6. Random review of the transfusion records from 2021 and 2022 revealed one of ten transfusion records of increased pulse rate without documentation of the nurse and/or physician accounting for the change. Patient ID 030985 (2/1/2022) Unit W0355221437207, exp 2/24/2022 pulse at 1100 hours: 66 pulse at 1115 hours: 101 7. An interview with the nursing director on 5/17/2022 at 1425 hours in the conference room confirmed the above findings. She acknowledged that the change in blood pressure and the increased pulse rate should have been investigated. |
| **D3029** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(2)<br><br>Test procedures. Retain a copy of each test procedure for at least 2 years after a |

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| | procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.<br><br>This STANDARD is not met as evidenced by:<br>Review of the individualized quality control plan (IQCP) and confirmed in interview the laboratory failed to retain the risk assessment documentation supporting the evaluation of the frequency and impact of failures throughout the pre-analytic, analytic, and post-analytic phases of testing for exempt microbiology media since it was evaluated in 2016. The findings include: 1. Review of the laboratory document titled "IQP and Risk Assessment for Exempt Microbiology Media" had the following risk frequency for the pre-analytic, analytic, and post-analytic phases of testing: 1 Sample: Pre-Analytical Patient Identification - Occasional Collection/Container volume - Occasionally Transport - Occasional Storage - Occasional 2 Testing Personnel: Analytical Training - Occasional Competency Assessment - Occasional Proficiency Testing - Occasional Staffing - Occasional 3 Reagents (media): Pre-Analytical Receiving/storage - Occasional Expiration dates - Occasional Visual inspection - Occasional 4 Environment: Analytical Temperature/Airflow/Humidity /Ventilation - Unlikely Utilities - Unlikely 5 Test Systems: Analytical Contamination - Unlikely Organism growth - Unlikely 6 Testing Results - Post-Analytical Review of released results - Unlikely Clinician feedback - Unlikely Surveyor queried for documentation to support the frequency of risk evaluated through the IQCP, and none was provided. 2. In an interview on 5/17/2022 at 14:20 hours, in the conference room, the Division Director of Laboratory Services confirmed that the laboratory did not retain the documentation to support the frequency for the risk assessment portion of the IQCP. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of proficiency testing documents and confirmed in interview, the laboratory failed to evaluate proficiency testing performances for the 2022 first event Hematology and Coagulation that were not evaluated or scored by a CMS-approved PT program reviewed for four of four non-graded hematology and coagulation PT results. The findings include: 1. Review of the American Proficiency Institute (API) 2022 Hematology / Coagulation 1st Event has the following 4 analytes/methods that were not scored by the CMS-approved PT program, API: Analyte / Method: IL ACL Top Family / HemosIL APTT-SP Sample - Performance COA-01 - Not Graded COA-02 - Not Graded COA-03 - Not Graded COA-04 - Not Graded COA-05 - Not Graded Analyte / Method: Platelet estimate (DIF)^ Sample - Performance DIF-01 - Not Graded Analyte / Method: Blood Cell ID (Educational) Sample - Performance ECI-01 - Not Graded ECI-02 - Not Graded ECI-03 - Not Graded ECI-04 - Not Graded ECI-05 - Not Graded Analyte / Method: Nucleated RBCs / Coulter UniCel DxH Sample - Performance COU-01 - Not Graded COU-02 - Not Graded 2. Surveyor queried for documentation that the performances were evaluated by the laboratory upon receipt, |

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| | and none was provided. 3. In an interview on 5/16/2022 at 11:50 hours, the general supervisor (GS) 1, confirmed that the laboratory did not self-evaluate the PT analytes/ methods that were not scored by the API PT agency. |
| **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 surveyor observations, review of laboratory policy, review of patient records, and interview with facility personnel, the laboratory failed to follow established policy for the speed and time that urine specimens are centrifuged for analysis of urine sediment for two of two days of testing. The findings included: 1. Based on surveyor observations at 14:53 hours on 5/16/2022, the laboratory centrifuge used to process urine specimens for urine sediment analysis was set to spin samples at 2,000 revolutions per minute (RPM) for 2 minutes. 2. Based on review of the laboratory policy "URINALYSIS", on page 7, the policy stated the following: " 13. If the urinalysis chemical strip shows that a microscopic is needed. Place a cap on the urine centrifuge tube and place in centrifuge for processing. Centrifuge specimen for 5 minutes at 1500-2000 rpm." 3. In an interview at 14:55 hours on 5/16/2022 in the conference room, the laboratory manager stated the laboratory had just adjusted the speed and time on the centrifuge the day before (5/15/2022). 38387 B. Based on review of laboratory and patient test records from 2020 to 2022 and confirmed in interview, the laboratory failed to ensure that a written procedure manual was available for one of ten tests reviewed: Urine Drug test with the Medtox Profile V Medtox Scan. Findings included: 1. Surveyor observations on 5/17/2022 at 1150 hours revealed the laboratory performed urine drug screens using the MedTox Profile V Medtox Scan (Kit # TA271G23, exp 7/31/2023). 2. Review of the laboratory policies revealed no documentation of a written procedure for Urine drug screens with the MedTox Profile V Medtox Scan. 3. Review of the CMS116 signed by the laboratory director on 5/11/2022 revealed the laboratory performed 279444 chemistry testing annually. 4. An interview with the general supervisor #1 on 5/17/2022 at 1155 hours in the conference room confirmed the above findings. |
| **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 |

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| | 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>Based on a review of the laboratory verification manual, laboratory documents, and confirmed in interview, the laboratory failed to include acceptability criteria for patients utilized in the normal range study for the assessment of Prothrombin Time (PT) new reagent lot for one of one new RecombiPlasTin lot assessments reviewed in 2021. The findings include: 1. Review of the "ACL Hemostasis Systems Performance Verification Manual" section "INR Calculation - ACL TOP family", subsection "Principles of Procedure" stated: "INR = (PT Patient/Mean Normal PT)^ISI Note that each lot number of thromboplastin will have a unique ISI value and the laboratory must establish the lot-specific mean of normal reference interval, which must be used as indicated. The geometric mean of the PT (seconds) normal reference interval, using the new lot number of thromboplastin." 2. Review of the form titled "Medical History Form for Normal Range Study" for the current lot N0705539 RecombiPlasTin in use had the following questions as part of patient screening for the normal range study performed in September 2021: "Medication (s): Are you on Antibiotics? Do you take Vitamin K? Do you take birth control? Do you take thyroid medication? Do you take daily aspirin? Does your diet consist of a large amount of green leafy vegetables (10-12 portions per week)?" 3. Surveyor queried the general supervisor (GS) 1 on 5/17 /2022 at 10:20 hours for the acceptance criteria for the above questions to determine which patients were used in the calculation of the geometric mean of the PT, and none was provided. 4. In an interview on 5/17/2022 at 10:30 hours, in the conference room, GS 1 confirmed that the laboratory did not have acceptability criteria included in the policy for the normal patient range study that is needed for the calculation of the normal patient PT geometric mean used in the calculation of INR. |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory verification manual, laboratory documents, and confirmed in interview, the laboratory failed to follow manufacturer instructions to use a geometric mean for the evaluation of a new normal patient mean for the assessment of Prothrombin Time (PT) new reagent lot for one of one new RecombiPlasTin lot assessments reviewed in 2021. The findings include: 1. Review of the "ACL Hemostasis Systems Performance Verification Manual" section "INR Calculation - ACL TOP family", subsection "Principles of Procedure" stated: "INR = (PT Patient/Mean Normal PT)^ISI Note that each lot number of thromboplastin will have a unique ISI value and the laboratory must establish the lot-specific mean of normal reference interval, which must be used as indicated. The geometric mean of |

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| | the PT (seconds) normal reference interval, using the new lot number of thromboplastin." 2. Review of a title-less printout with a header of "Hemosil Lot N0705539 Exp 7/2022 ISI: 0.990" had the following normal patient PT results and mean calculation: 1 - 11.2 2 - 10.7 3 - 11.6 4 - 9.7 5 - 10.6 6 - 12 7 - 10.9 8 - 10.7 9 - 10.5 10 - 9.9 11 - 17.5 12 - 10.9 13 - 9.9 14 - 11.6 15 - 10.8 16 - 11.3 17 - 12.7 18 - 14.6 19 - 11.7 20 - 11.6 21 - 12.8 22 - 11.8 23 - 12.5 24 - 11.4 25 - 11.2 Mean: 11.604 The geometric mean, as calculated by the surveyor, resulted to be 11.51112. 3. In an interview 5/17/2022 at 10:00 hours, in the conference room, the Division Director of Laboratory Services confirmed that the normal patient mean used for the assessment of new lot PT reagent was not a geometric mean. |
| **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 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 calibration records and interview with facility personnel, the laboratory failed to perform calibration verification procedures with at least a minimal, mid, and maximum value for three analytes - Sodium, Potassium, and Chloride, at least every six months for 2021. The findings included: 1. Based on review of calibration records, Sodium, Potassium, and Chloride analytes are calibrated with two solutions: STD A and STD B. 2. At 16:15 hours on 5/17/2022 in the laboratory, the surveyor requested calibration verification records for 2021 that included at least a minimal, mid, and maximum value. 3. In an interview at 16:15 hours on 5/17/2022 in the laboratory, the Laboratory Manager confirmed the laboratory had not performed calibration verification for Sodium, Potassium, or Chloride at least every six months in 2021. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The |

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| | laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory quality control and patient test records from December 2021 to May 2022, and confirmed in interview, the laboratory failed to monitor over time the accuracy and precision of four of four quality control materials reviewed for blood gas testing on the ABL blood gas analyzer. Findings included: 1. Random review of the laboratory records from December 2021 to May 2022 revealed the laboratory used the following four internal quality control materials for blood gas testing on the ABL blood gas analyzer C8301 C8302 C8303 C8304 2. Review of the laboratory records for the above dates revealed no documentation the laboratory monitored over time the above quality controls. 3. Review of the CMS116 revealed the laboratory performed 279444 chemistry testing annually. 4. An interview with the general supervisor #1 on 5/17/2022 at 1430 hours in the conference room confirmed the above findings. |
| **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 laboratory and patient test records from 2020 to 2022 and confirmed in interview, the laboratory failed to document an INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) to reduce the frequency to every new lot of quality control for one of five tests reviewed: Urine Drug Screen with the Medtox Profile V Medtox Scan. Findings included: 1. Surveyor observations on 5/17/2022 at 1150 hours revealed the laboratory performed urine drug screens using the MedTox Profile V Medtox Scan (Kit # TA271G23, exp 7/31/2023). 2. Review of the laboratory quality control records from December 2021 to May 2022 revealed the laboratory performed quality control for MedTox drug screens on the following five days: Positive Control lot CC0140, exp 11/30/2023 3/5/2022, 4/22/2022 Negative Control lot N00168-2, exp 10/31/2022 1/11/2022; 2/23/2022; 12/7/21 3. Review of the laboratory and patient test records available revealed no documentation of an IQCP to reduce the frequency of quality control for MedTox drug screens. 4. Review of the CMS116 signed by the laboratory director on 5/11/2022 revealed the laboratory performed 279444 chemistry testing annually. 5. An interview with the general |

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| | supervisor #1 on 5/17/2022 at 1155 hours in the conference room confirmed the above findings. 45469 II. Based on a review of Individual Quality Control Plan (IQCP) documents and confirmed in interview, the laboratory failed to evaluate the frequency of potential failures in their risk assessment portion of the IQCP for Serum HCG testing for a review period of 2021. The findings include: 1. Review of the IQCP for serum HCG testing lacked an evaluation of the frequency at which errors are likely to occur during the pre-analytical, analytical, and post-analytical phases of testing. 2. In an interview on 5/17/2022 at 14:20 hours, in the conference room, the Division Director of Laboratory Services confirmed that an evaluation of the frequency at which errors are likely to occur during all phases of testing was missing from the IQCP. |
| **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>Review of laboratory quality control documents, patient testing records, and confirmed in interview, the laboratory failed to perform quality control every day of patient testing for two tests kits, Rotavirus and C. Diff check, for six of six patients, tested in April 2022. The findings include: 1. Review of the QC records for April 2022 had the following intervals for QC testing: 3/28/2022 C. Diff Quick Chek Kit Lot 0821332 Exp 11/1/2022 Next QC Due: [Blank] 4/1/2022 Rotavirus Kit Lot 7869.392 Exp 11/1/2023 Next QC Due: 5/1/2022 Surveyor queried for documentation to support the reduced frequency of QC from every day of patient testing, and none was provided. 2. Review of patient testing has the following six patients tested on days where quality control was not performed: Date - Test Specimen ID - Test 4/13 /2022 - 103M0026 - Rotavirus 4/16/2022 - 106M0013 - C. diff 4/20/2022 - 109M0027 - C. diff 4/28/2022 - 118M0008 - C. diff 4/29/2022 - 119M0023 - C. diff 4 /30/2022 - 120M0008 - C. diff 3. In an interview on 5/17/2022 at 15:00 hours, in the conference room, the general supervisor (GS) 1 confirmed that the laboratory was not performing QC every day of patient testing for Rotavirus or the C.Diff quick chek kit testing. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of quality control (QC) documents, patient test results, and confirmed in interview, the laboratory failed to perform QC every day of patient testing for the Vitek microbiology susceptibility for 51 of 51 patients reviewed from April 18, 2022 to April 30, 2022. 1. Review of automated susceptibility testing (AST) QC documents for gram-positive (GP) and gram-negative(GN) organisms from April 18 to April 30th 2022 for the Vitek, had QC testing being performed at weekly intervals. Surveyor queried for documentation to support the reduced frequency of QC from every day of patient testing, and none was provided. The following days had QC documented from April 18 to April 30, 2022: AST - GP67 - Performed 4/25/2022 AST - GP67 - Performed 4/18/2022 AST - GN69 - performed 4/25/2022 AST - GN69 - Performed 4/18/2022 2. Review of test results from April 18, 2022 to April 30, 2022, had 51 patients with AST performed on days where QC had not been performed. A sampling of these patients includes: Sample ID - AST Card - Date Tested 4437398 - GN69, GN67 - 4/30/2022 5301267 - GP67 - 4/28/2022 5309413 - GP67 - 4/28/2022 4811497 - GP67 - 4/27/2022 4942121 - GN69 - 4/27/2022 4750967 - GN69 - 4/27/2022 4502821 - GN69 - 4/27/2022 3. In an interview on 5/17/2022 at 15:00 hours, in the conference room, the general supervisor (GS)1 confirmed that microbial susceptibility was not performed every day of patient testing. |
| **D5543** | HEMATOLOGY<br>CFR(s): 493.1269(a)(d)<br><br>(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (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 the laboratory policies and procedures, patient testing records, and interview with facility personnel, the laboratory failed to perform one control material each 8 hours of operation AND test control materials in duplicate for four of four specimens tested between 10/4/2021 and 4/13/2022. The findings included: 1. Based on review of the laboratory procedure "QUALITY ASSURANCE AND QUALITY CONTROL IN HEMATOLOGY", on page 8 under section QUALITY CONTROL OF MANUAL PROCEDURES, the procedure stated the following: "Manual WBC counts are not performed on peripheral blood in our laboratory. The laboratory can perform a WBC slide estimate when indicated. Manual WBC counts are performed on CSF fluid using a Neubauer hemacytometer. Commercial CSF Cell count control material is tested each day of patient testing. Control values that fall outside acceptable ranges must be repeated and/or the discrepancy must be resolved prior to reporting patient results. Ranges for commercial CSF Cell count control are taken from the manufacturer insert. Manual RBC counts are performed only on CSF. Commercial CSF Cell count control material is tested each day of patient testing. Control values that fall outside acceptable ranges must be repeated and/or the discrepancy must be resolved prior to reporting patient results. Ranges for commercial CSF cell count control are taken from the manufacturer insert." 2. Based on review of patient test records, the following specimens were analyzed between 10/4/2021 and 4 /13/2022 in the absence of commercial quality control materials: 21TP-277H0077 21TP-285H0065 22TP-069H0060 22TP-103H0059 3. In an interview at 14:28 hours on 5/16/2022 in the conference room, the Laboratory Manager confirmed the laboratory did not have any commercial quality control materials available for the |

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| | hemacytometer and had not used quality control materials as required by the laboratory policy. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 the laboratory policy, surveyor observations, review of laboratory records from 2020 to 2022, and confirmed in interview, the laboratory failed to inspect the alarm system for the laboratory freezer that stored blood products (FFP) in 2020 and 2021. The findings were: 1. Review of the laboratory policies available revealed no policy for the blood bank freezer manual alarm check. 2. Surveyor observation on 5/17/2022 revealed FFP (Fresh Frozen Plasma) stored frozen in the laboratory freezer. 3. Review of the laboratory records from 2020 to 2022 revealed no documentation the laboratory inspected the alarm system for the above freezer for 2020 and 2021. 4. Review of the laboratory records revealed the lab performed 204 compatibility testing annually. 5. An interview with the testing person # 2 on 5/17 /2022 at 1015 hours in the laboratory confirmed the above findings. |
| **D5559** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(e)(f)<br><br>(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 the laboratory policy, laboratory and patient test records from 2020 to 2022, and confirmed in interview, the laboratory failed to follow its policy to investigate all transfusion reactions for one of one transfusion reaction reviewed. Findings included: 1. Review of laboratory records from 2020 to 2022 revealed one suspected transfusion reaction identified for Patient ID 169388 on 11/01/2021. 2. Review of the transfusion record for W035221333949 on 11/1/2021 revealed the following reaction symptom: "chest tightness" and the following nursing intervention: " transfusion stopped; IV tubing and remaining blood to lab." 3. Review of the laboratory policy Transfusion Reaction Investigation (Policy # BB-012) revealed the following laboratory protocol: "Clerical Check Initiate a Transfusion Reaction |

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| | Investigation form. Record at the top of the form the patient's name, hospital number, location, age, sex, medical record number, your name, and the date and time the investigation was begun. A. Verify post-transfusion documentation, original transfusion documentation, and pre-transfusion documentation B. Verify that all specimens used for crossmatch are properly labeled. Initial Laboratory Investigation 1. Examine pre-transfusion and post-transfusion specimens for pink or red discoloration (hemolysis), or yellow or brownish discoloration (icteric). Record the presence or absence of hemolysis or icteric on the Transfusion Reaction Investigation form. 2. Examine each unit implicated in the suspected reaction for hemolysis in the supernatant plasma, discoloration in plasma or cell mass, clots or other abnormalities. If the cells or plasma in the donor unit have a brownish or purple discoloration, or if there are clots or abnormal masses in the liquid blood, the plasma is opaque or muddy there is gas or a peculiar odor, suspect bacterial contamination. Record any abnormalities on the Transfusion Reaction investigation form. 3. Perform a DAT on the pre-transfusion and post transfusion samples and record the result on the form. 4. Perform an ABO and Rh type on both the pre and post transfusion specimens. Record the results on the form. Notification of Medical Director 1. If notified by the Nursing Service of a suspected transfusion reaction: Perform the appropriate investigation described above before contacting the pathologist. If there are no clerical or technical errors discovered, or there is laboratory evidence of an acute hemolytic transfusion reaction, contact the pathologist and describe the results of your investigation. If the laboratory investigation reveals no clerical or technical errors and there is no laboratory evidence of an acute hemolytic transfusion reaction, leave all forms in the laboratory manager's box for the pathologist to review. There is no requirement to contact the pathologist at this point." 4. Review of the laboratory records for the suspected transfusion for Patient ID 169388 on 10/31/2021 revealed no documentation of the Transfusion Reaction investigation to include the above investigations. 5. An interview with the testing person # 2 at 5/17/2022 at 1115 hours in the laboratory confirmed the above findings. She acknowledged that the laboratory only did a DAT testing and no other investigation was performed. |
| **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 surveyor observations, records review, and interview with facility personnel, the laboratory failed to evaluate the relationship between two of two chemistry analyzers at least twice annually for 2021. The findings included: 1. Based on surveyor observations at 10:41 hours on 5/17/2022 in the laboratory, the laboratory utilized two chemistry analyzers for routine patient analysis: a Roche Cobas and Siemens Dimension. 2. In an interview at 10:41 hours on 5/17/2022 in the laboratory with the Division Director of Laboratory Services, the surveyor requested documentation of the laboratory evaluating the relationship between the two analyzers for the analytes that analyzed on both platforms. The Division Director of Laboratory Services stated the laboratory had not evaluated the relationship between the two analyzers in 2021. The following analytes are some of the analytes performed on both |

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| | chemistry analyzers: Albumin ALP ALT AST Chloride CO2 T4 TSH T3 Amylase Total Bilirubin Calcium CK Glucose Potassium BUN |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's quality assurance records, policies and procedures, and confirmed in interview with the Laboratory Manager, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings included: 1. The laboratory failed to perform calibration verification procedures with at least a minimal, mid, and maximum value for analytes three analytes - Sodium, Potassium, and Chloride, at least every six months for 2021. Refer to D5439. 2. The laboratory failed to monitor over time the accuracy and precision of four of four quality control materials reviewed for blood gas testing on the ABL blood gas analyzer. Refer to D5441. 3. The laboratory failed to document an INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) to reduce the frequency to every new lot of quality control for one of five tests reviewed: Urine Drug Screen with the Medtox Profile V Medtox Scan. Refer to D5445. 4. The laboratory failed to perform one control material each 8 hours of operation AND test control materials in duplicate for four of four specimens tested between 10/4/2021 and 4/13/2022. Refer to D5543. 5. The laboratory failed to inspect the alarm system for the laboratory freezer that stored blood products (FFP) in 2020 and 2021. Refer to D5555. 6. The laboratory failed to follow its policy to investigate all transfusion reactions for one of one transfusion reaction reviewed. Refer to D5559. 7. The laboratory failed to evaluate the relationship between two of two chemistry analyzers at least twice annually for 2021. Refer to D5775. |
| **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 a review of the Centers for Medicare and Medicaid (CMS) personnel form 209, laboratory training records, and confirmed in interview, the laboratory failed to have documentation of training for one out of six testing persons for microbiology since July of 2021 . The findings include: 1. Review of laboratory training documents for 2021 and 2022 for testing personnel (TP) 3 did not include documentation of training for microbiology. Surveyor queried 5/16/2022 at 10:30 hours, in the |

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| | conference room, if TP 3 was performing microbiology testing and the general supervisor (GS) 1 confirmed TP3 was. 2. In an interview 5/16/2022 at 10:35 hours, in the conference room, GS 1 confirmed that the technical consultant failed to documentation for TP3 was missing. |