Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0705327	07/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
General John J Pershing Memorial Hospital	130 E Lockling, Brookfield, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of blood bank procedures, blood bank quality control (QC) logs, blood bank patient records/logs, the laboratory's information system (LIS), blood bank alarm inspections and interviews, the laboratory failed to meet the condition of analytic systems for the sub-category immunohematology. The laboratory failed to follow procedure for crossmatching blood products by not ensuring a physician order for blood products and documentation of the release of units was recorded in the laboratory information system (LIS) (Refer to D5401); the laboratory failed to document quality control for eleven testing days in 2022 and failed to provide a procedure for checking patient history in blood bank (Refer to D5551); and the laboratory failed to correctly perform refrigerator alarm inspections according to the laboratory's established procedure (Refer to D5555).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of blood bank procedures, blood bank quality control (QC) logs, blood bank patient records, the laboratory's information system (LIS) and interview with the general supervisor (GS) #1, the laboratory failed to follow procedure for crossmatching blood products. Findings: 1. Review of "Blood Bank Techs Guide for Crossmatching" procedure states "ER, Inpatient, and Outpatient nurses only put orders for RBC and not Crossmatch." and "Go to Final Disposition on the app bar and make sure you are in transfuse mode. Type the product number of the blood unit to be transfused. Then click save." 2. Review of blood bank QC logs and blood bank patient records showed patient #1 had one unit of packed red blood cells (RBC), unit number W045022044345 crossmatched on May 14, 2022 and transfused on May 15, 2022 at 2: 45 PM and two units of packed RBCs, unit numbers W045022048877 and W045022042866 crossmatched on May 15, 2022 and transfused on May 16, 2022 at 11:50 AM and May 17, 2022 at 1:30 PM. 3. Review of blood bank patient records in the laboratory's LIS showed no physician order for RBC or documentation of crossmatch and transfusion for units W045022044345 and W045022042866. 4. Interview with the GS #1 on June 28, 2022 at 2:00 PM confirmed the laboratory failed to follow procedure for crossmatching blood products by not ensuring a physician order for blood products and documentation of the release of units was recorded in the LIS.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Lack of humidity logs in the respiratory department, room temperature logs in the respiratory department and interview with general supervisor (GS) #4, the laboratory failed to define correctly and meet manufacturer's criteria for humidity ranges and room temperature ranges essential to proper test system operation consistent with manufacturer's instructions in 2021 and to date June 28, 2022. Finding: 1. Review of manufacturer's instructions for the Gem 5000 stated the relative humidity must be "15 percent to 85 percent" and the room temperature must be "12 degrees Celsius to 32 degrees Celsius". 2. The laboratory could not provide humidity or room temperature logs for the respiratory department. 3. Interview with the GS #4 on June 28, 2022 at 12:00 PM, confirmed that no criteria was set to monitor humidity and room temperature ranges consistent with manufacturers's instructions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

	when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of hematology area and interview with general supervisor (GS) #1, the laboratory failed to identify the white blood cell (WBC) staining material and include preparation and expiration dates. Findings: 1. Observation of the hematology area showed two unlabeled containers with no preparation or expiration dates. 2. Interview with GS #1 on June 28, 2022 at 1:00 PM confirmed the laboratory failed to identify the WBC staining material and include preparation and expiration dates.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of Gem 5000 blood gas analyzer performance specifications, Vitros 5600 chemistry analyzer performance specifications, Sysmex XN 550 hematology performance specifications and interview with the general supervisor (GS) #1, the laboratory failed to ensure verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population. Findings: 1. Review of the Gem 5000 blood gas analyzer performance specifications showed no verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population for the analytes: pH, pCO2 and pO2 since the start of patient testing in January 2021. 2. Review of the Vitros 5600 chemistry analyzer performance specifications showed no verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population for the analytes: sodium, potassium, chloride, CO2, alkaline phosphatase, AST, ALT, glucose, creatinine, calcium, total protein, albumin, bilirubin, BUN and phosphorus since the start of patient testing in May 2021. 3. Review of the Sysmex XN 550 hematology analyzers performance specifications showed no verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelets since the start of patient testing in May 2021 4. Interview with the GS #1 on June 28, 2022 at 11:00 AM confirmed the laboratory failed to ensure verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Vitros 350 chemistry analyzer quality control (QC) logs, BioRad Liquid Assayed Multiqual Control package insert, and interview with general supervisor (GS) #1, the laboratory failed to establish or verify the criteria for acceptability of chemistry QC. Findings: 1. Review of QC on the Vitros 350 chemistry analyzer for May 28, 2022 to date June 28, 2022 showed BioRad level 1 lot number 45931 and level 2 lot number 45932. The ranges in the Vitros 350 chemistry analyzer were: creatine kinase: level 1 39.4-76.6 U/L Level 2 153.6-240.4 U/L 2. Review of BioRad Liquid Assayed Multiqual Control package insert for level 1 lot number 45931 and level 2 lot number 45932 showed acceptable ranges: creatine kinase: level 1 54.0-83.3 U/L Level 2 165-232 U/L 3. Review of May 28, 2022 to date June 28, 2022 Vitros 350 chemistry analyzer QC logs for creatine kinase showed QC was not within manufacturer's acceptable limits for 20 of 30 testing days. 4. Interview with the GS #1 on June 28, 2022 at 11:30 AM confirmed the laboratory failed to establish or verify the criteria for acceptability of chemistry QC.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of hematology records and interview with the general supervisor (GS) #1, the laboratory failed to document the quality of staining materials each day of use for manual differentials for 2021 and to date June 28, 2022.. Findings: 1. Lack of hematology records showed the laboratory failed to document the quality of staining materials each day of use for manual differentials. 2. Interview with GS #1 on June 28, 2022 at 1:00 PM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (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. This STANDARD is not met as evidenced by: 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 for eleven testing days in 2022 and failed to provide a procedure for checking patient history in blood bank. Findings: 1. Review of the laboratory's blood bank policy "Confirmation of Donor Unit Type" states, " Perform QC. If QC produces expected results, proceed." 2. Review of 2022 blood bank patient testing logs showed donor unit retype testing was performed on January 29, 2022, January 25, 2022, February 8, 2022, February 25, 2022, March 8, 2022, March 22, 2022, April 5, 2022, April 19, 2022, May 3, 2022, May 18, 2022, and May 31, 2022. 3. Review of 2022 blood bank QC logs show no documented QC on January 29, 2022, January 25, 2022, February 8, 2022, February 25, 2022, March 8, 2022, March 22, 2022, April 5, 2022, April 19, 2022, May 3, 2022, May 18, 2022, and May 31, 2022. 4. Review of blood bank procedures showed no procedure for checking patient history prior to performing blood bank procedures. 5. Interview with the GS #1 on June 28, 2022 at 1:00 PM confirmed the laboratory failed to document quality control for eleven testing days in 2022 and failed to provide a blood bank procedure for checking patient history.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (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. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, blood bank alarm inspections, and interview with the general supervisor (GS) #1, the laboratory failed to correctly perform refrigerator alarm inspections according to the laboratory's established procedure. Findings: 1. Review of blood bank procedure, "Blood Bank Alarm Testing" states, "High Alarm, Place the sensor and a calibrated thermometer in a container of water at 3 degrees Celsius to 4 degrees Celsius. Slowly add warm water with constant mixing. The alarm should sound when the temperature approaches 6 degrees Celsius. Compare the thermometer reading with the recorder chart. Record the high temperature on the QC form. Low Alarm, Place the sensor and a calibrated thermometer in a container of water at 3 degrees Celsius to 4 degrees Celsius. Add crushed ice slowly while mixing. The alarm should sound when the temperature approaches 1 degree Celsius. Compare the thermometer reading with the recorder chart. Record the low temperature on the QC form. All results are recorded on the

	Blood Bank Refrigerator Quarterly Alarm Checks." 2. Review of blood bank alarm inspection showed alarm inspections for 2020, 2021 and to date June 28, 2022 were not performed according to procedure. 3. Interview with the GS #1 on June 28, 2022 at 11:40 AM confirmed, the laboratory failed to correctly perform blood bank refrigerator alarm inspections according to the laboratory's established procedure.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records, training documents and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to identify and document training needs for two of eleven testing personnel (TP) in 2021. Findings: 1. Review of personnel records and training documents showed the laboratory could not provide documentation for initial training and competency for TP #4 and TP #6. TP #4 started with the laboratory in October 2021 and TP #6 started with the laboratory in June 2021. 2. Interview with the GS #1 on June 28, 2022 at 2:00 PM, confirmed the technical supervisor failed to identify and document training needs for two of eleven TP in 2021.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to evaluate and document the performance of one of eleven testing personnel (TP) at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of 2020 and 2021 performance evaluations showed the TS failed to perform the semi-annual competency evaluation for TP #6. 2. Interview with the GS #1 on June 28, 2022 at 2:00 PM, confirmed the TS failed to evaluate and document the performance of one of eleven TP at least semiannually during the first year the individual tests patient specimens.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

	to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the general supervisor (GS) #1, the technical supervisor (TS) failed to evaluate and document competency /performance for four of eleven testing personnel (TP) at least annually during 2020 and 2021. Findings: 1. Review of personnel records showed the TS did not evaluate competency/performance for TP #1, TP #2, TP #3, and TP #5 performing patient testing during 2020 and 2021. 2. Interview with GS #1 on June 28, 2022 at 2:00 PM, confirmed competency/performance evaluations were not conducted at least annually in 2020 and 2021.