Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470030	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Purcell Municipal Hospital	2301 N 9th Ave, Purcell, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 09/21,22,23,24,25/2020. Immediate Jeopardy was determined during the survey due to issues identified with Blood Bank testing. The laboratory voluntarily ceased patient testing, which abated the Immediate Jeopardy. The laboratory was found out of compliance with the following CLIA regulations: 493.1217; D5026: Immunohematology 493.1250; D5400: Analytic Systems 493.1443; D6000: Moderate Complexity Laboratory Director 493.1409; D6033: Technical Consultant 493.1441; D6076: High Complexity Laboratory Director 493.1447; D6108: Technical Supervisor The findings were reviewed with general supervisor/technical consultant #1 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory director or designee failed to sign proficiency testing attestation statements for 2 of 32 events. Findings include: (1) On 09/21/20201, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following for 2 of 32 events: (a) Q1 Chemistry 2019 Event - The

	attestation statement had not been signed by the laboratory director or designee; (a) Q3 Nonchemistry 2019 Event - The attestation statement had not been signed by the laboratory director or designee. (2) Surveyor #2 reviewed the findings with the general supervisor/technical consultant #1 and technical consultant #2. The technical consultant #2 stated on 09/21/2021 at 03:00 pm, the attestation statements had not been signed by the laboratory director or designee.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to ensure the requirements were met for the specialty of Immunohematology. Findings include: (1) The laboratory failed to have written procedures for Blood Bank testing. Refer to D5401; (2) The laboratory failed to perform function checks on the blood bank centrifuge as required by the manufacturer. Refer to D5431; (3) The laboratory failed to provide evidence a negative and positive control material had been performed each day of patient Immunohematology testing. Refer to D5449; (4) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (5) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1, the laboratory failed to have a written competency policy for the general supervisor and technical consultant based on the job responsibilities as listed in Subpart M. Findings include: (1) On 09/21/2020, surveyor #2 reviewed personnel records for competency assessments performed during 2019 through 09/21/2020. There was no evidence competencies had been performed for the general supervisor, technical consultant #1, and technical consultant #2 based on their job responsibilities; (2) Surveyor #2 asked the general supervisor/technical consultant #1 if a written policy to evaluate the positions based on job responsibilities was available and if competencies had been performed during the review period. The general supervisor /technical consultant #1 stated on 09/21/2020 at 1:30 pm a policy to evaluate the general supervisor and technical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to verify the accuracy of Cerebral Spinal Fluid manual cell counts at least twice annually. Findings include: (1) On 09/21/2021 at 01:15 pm, the general supervisor/technical consultant #1 and technical consultant #2 stated manual Cerebral Spinal Fluid cell counts for WBC (White Blood Cells) and RBC (Red Blood Cells) were performed using a hemacytometer; (2) Surveyor #2 reviewed 2019 and 2020 records. There was no documentation which would confirm that the accuracy of the interpretations had been verified in 2019 and to date (09/21/2020) in 2020; (3) Surveyor #2 asked the general supervisor/technical consultant #1 and technical consultant #2, if manual Cerebral Spinal Fluid cell counts had been verified for accuracy in 2019 and to date in 2020. Technical consultant #2 stated on 09/21/2020 at 03:35 pm the accuracy of the testing had not been been verified.
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 a review of written policies and procedures, manufacturer's instructions, observation, and interview with general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to monitor and evaluate the overall quality of analytic systems. Findings include: (1) The laboratory failed to have written procedures for Blood Gas testing. Refer to D5401; (2) The laboratory failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (3) The laboratory failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (4) The laboratory failed to verify the reportable range for a new test method; and failed to ensure the the performance specifications of a new test system were approved by the laboratory. Refer to D5421; (5) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (6) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (7) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Hematology, Coagulation, and Chemistry testing. Refer to D5441; (8) The laboratory failed to perform quality control as stated in the IQCP for Clostridium difficile testing. Refer to D5445; (9) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.

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 a review of written policies and procedures, and interview with general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to have written procedures for Blood Bank and Blood Gas testing. Findings include: BLOOD BANK (1) On 09/21/2021 at 11:45, technical consultant #2 stated to surveyor #2 the laboratory performed ABO/Rh Type, Antibody Screen, and Compatiblity testing using the Ortho ID MTS Gel system; (2) Surveyor #2 requested the procedure manual for the testing. Technical consultant #2 stated on 09/21/2021 at 02:28 pm, a procedure manual was not available for the above testing. BLOOD GAS (1) On 09/21/2021 at 11:10 am, technical consultant #2 stated to surveyor #2 that Arterial Blood Gas Testing was performed using the EPOC analyzer beginning 08/31 /2020; (2) Surveyor #2 asked the general supervisor/technical consultant #1 and technical consultant #2 for the EPOC procedure manual; (3) Technical consultant #2 stated on 09/23/2021 at 01:17 pm a procedure manual was not available for the above testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On 09/21/2021 at 11:10 am, technical consultant #2 stated the following to the surveyor: (a) The laboratory performed the following tests on the Alere Triage Analyzer: (i) D-Dimer (ii) CKMB (iii) Urine Drug Screen (b) IQCP's (Individualized Quality Control Plan) had been developed for the test systems. (2) Survyor #2 reviewed the IQCP's (dated as effective on 01/07/2016) and identified the QCP's (Quality Control Plans) had not been approved, signed, and dated by the laboratory director; (3) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2 who both stated on 09/23/2020 at 02:30 pm the QCP's had not been approved, signed, and dated by the laboratory director.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to ensure control materials were not used beyond the expiration date. Findings include: (1) On 09/21/2020 at 11:30 am, surveyor #2 observed the contents of the laboratory refrigerator and identified the following expired material: (a) BioRad Liquichek Specialty Immunoassay Control Level 1 (lot #60241) - Printed on the bottle was the manufacturer's expiration date of 08/31/2020; (b) BioRad Liquichek Specialty Immunoassay Control Level 1 (lot #60242) - Printed on the bottle was the manufacturer's expiration date of 08/31/2020. (2) The technical consultant #2 stated the QC (Quality Control) materials were used to perform Vitamin D testing on the Beckman Coulter DxC 6000i; (3) The QC material was shown to the general supervisor/technical consultant #1 and technical consultant #2. The general supervisor/technical consultant #1 and technical consultant #2 both stated on 09/21/2020 at 11:40 am were not aware the material had expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to verify the reportable range for a new test method; and failed to ensure the the performance specifications of a new test system were approved by the laboratory. Findings include: (1) On 09/21/2020 at 11:10 am, technical consultant #2 stated to surveyor #2 that Arterial Blood Gas Testing was performed using the EPOC analyzer beginning 08/31/2020; (2) Surveyor #2 reviewed performance specification records for the analyzer and identified the following: (a) No evidence the reportable range had been verified; (b) No evidence the performance specifications of the new test system were approved by the laboratory. (3) Surveyor #2 reviewed the validation records with the general supervisor/technical consultant #1 and technical consultant #2. Technical consultant #2 stated on 09/23/2020 at 02:37 pm the laboratory had not verified the reportable range and approved the performance specifications as indicated above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the

	general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: DC-10 GLYCOHEMOGLOBIN TESTING (1) On 09 /21/2020 at 11:47 am, the general supervisor/technical consultant #1 and technical consultant #2 stated to surveyor #2 that Glycohemoglobin testing was performed on the D-10 analyzer; (2) Surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for daily maintenance were as follows: (a) Check Method Settings (b) Check Reagent Levels (c) Check Reagent Onboard Expiration Date(s) (d) Cartridge Injection Count (e) Check Waste Level (f) Pressure Reading (g) Check for Leaks (h) Check Paper Supply (i) Remove Samples (j) Wipe Spills (3) Surveyor #2 then reviewed maintenance records for 4 months (February 2020 through May 2020). There was no evidence the daily maintenance had been performed: (a) Between 04/20/2020 and 04 /24/2020 (b) Between 04/27/2020 and 05/04/2020 (c) Between 05/15/2020 and 05/19 /2020 (4) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2, who stated on 09/22/2021 at 02:47 pm the maintenance had not been performed as required as indicated above. IRIS URINALYSIS TESTING (1) On 09/21/2020 at 11:40 am, the general supervisor /technical consultant #1 and technical consultant #2 stated to surveyor #2 that urinalysis testing was performed on the Iris analyzer; (2) Surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for monthly maintenance were as follows: (a) Perform Instrument Calibration (b) Perform Backup (3) Surveyor #2 then reviewed maintenance records for 6 months (April 2019 through October 2019). There was no evidence the monthly maintenance had been performed: (a) Between 05/06/2019 and 07/01/2019 (4) Surveyor #2 reviewed the records with the general supervisor /technical consultant #1 and technical consultant #2, who stated on 09/23/2021 at 04: 27 pm the maintenance had not been performed as required as indicated above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2 and the general supervisor/technical consultant #1, the laboratory failed to perform function checks on the blood bank centrifuge as required by the manufacturer. Findings include: (1) On 09/21/2020 at 11:45, technical consultant #2 stated to surveyor #2 the laboratory performed ABO/Rh Type, Antibody Screen, and Compatiblity testing using the Ortho ID MTS Gel system; (2) On 09/23 /2020, surveyor #2 reviewed the manufacturer's instructions for the MTS centrifuge used to process the specimens. The instructions stated the following for confirming daily checks: (a) "Check that the tachometer RPM display reads 895 +/- 25"; (b) "Check that the timer display begins at 10:00 minutes and counts down (9:59, 9:58, etc.). When the timer reaches zero, the display becomes blank". (3) Surveyor #2 reviewed records for patient testing performed in May and August 2019; and January through July 2020. There was no documentation to prove the tachometer RPM and timer displays had been checked for 2 of 5 days in 2019 and 51 of 51 days in 2020

	when patient Type and Screen Testing (consisted of ABO/Rh and Antibody Screen) and Crossmatch Testing (consisted of ABO/Rh, Antibody Screen, and Compatibility testing) had been performed; (4) On 09/24/2020, surveyor #2 reviewed the records with the general supervisor/technical consultant #1 who stated there was no documentation to prove the tachometer and timer displays had not been checked; (5) The following patient testing had been performed when the tachometer display and timer display had not been documented as observed (number represents medical record number): (a) Patient #32183 - Type and Screen performed on 05/03/2020 (b) Patient #1817 - ABO/Rh Type performed on 08/21/2020 (c) Patient #228712- ABO /Rh type performed on 01/09/2021 (d) Patient #224992- Crossmatch performed on 01 /10/2021 (e) Patient #1817 - Type and Screen performed on 01/13/2020 (f) Patient #1773 - Crossmatch performed on 01/15/2020 (g) Patient #3442 - Crossmatch performed on 01/18/2020 (h) Patient #1817 - Crossmatch performed on 01/24/2020 (i) Patient #80027 - Crossmatch performed on 01/26/2020 (j) Patient #228906 - Type and Screen performed on 01/27/2020 (k) Patient #210543 - Crossmatch performed on 01 /27/2020 (l) Patient #228968 - Crossmatch performed on 02/01/2020 (m) Patient #226671 - Crossmatch performed on 02/02/2020 (n) Patient #228967 - Crossmatch performed on 02/03/2020 (o) Patient #228207 - Type and Screen performed on 02/06 /2020 (p) Patient #228967 - Crossmatch performed on 02/20/2020 (q) Patient #205928 - Crossmatch performed on 02/20/2020 (r) Patient #229211 - ABO/Rh type performed on 02/22/2020 (s) Patient #2912 - Type and Screen performed on 02/24 /2020 (t) Patient #8636 - Crossmatch performed on 02/28/2020 (u) Patient #1046082 - Crossmatch performed on 02/29/2020 (v) Patient #211513 - Crossmatch performed on 03/02/2020 (w) Patient #215103 - Crossmatch performed on 03/06/2020 (x) Patient #17743 - Crossmatch performed on 03/11/2020 (y) Patient #25006 - Crossmatch performed on 03/16/2020 (z) Patient #229544 - Crossmatch performed on 03/27/2020 (aa) Patient #26735 - Crossmatch performed on 04/03/2020 (bb) Patient #19753 - ABO/Rh type performed on 04/04/2020 (cc) Patient #17743 - Crossmatch performed on 04/06/2020 (dd) Patient #217147 - ABO/Rh type performed on 04/08/2020 (ee) Patient #16063 - Crossmatch performed on 04/14/2020 (ff) Patient #25103 - Crossmatch performed on 04/18/2020 (gg) Patient #80027 - Crossmatch performed on 04/21/2020 (hh) Patient #35248 - Antibody screen performed on 04/27/2020 (ii) Patient #229709 - Crossmatch performed on 04/28/2020 (jj) Patient #43938 - Crossmatch performed on 05/02/2020 (kk) Patient #47231 -Type and Screen performed on 05/05/2020 (ll) Patient #41626 - Type and Screen performed on 05/07 /2020; (mm) Patient #21059 - Crossmatch performed on 05/28/2020 (nn) Patient #22059 - Crossmatch performed on 06/03/2020 (oo) Patient #17743 - Crossmatch performed on 06/17/2020 (pp) Patient #28112 - Type and Screen performe on 06/18 /2020 (qq) Patient #7967 - Crossmatch performed on 06/18/2020 (rr) Patient #74333 - Crossmatch performed on 06/22/2020 (ss) Patient #91692 - Crossmatch performed on 06/24/2020 (tt) Patient #227906 - ABO/Rh performed on 06/27/2020 (uu) Patient #29464 - Crossmatch performed on 07/01/2020 (vv) Patient #66571 - Crossmatch performed on 07/09/2020 (ww) Patient #25103 - Crossmatch performed on 07/10 /2020 (xx) Patient #34880 - Crossmatch performed on 07/14/2020 (yy) Patient #17743 - Crossmatch performed on 07/15/2020 (zz) Patient #45029 - Crossmatch performed on 07/16/2020 (aaa) Patient #227379 - Crossmatch performed on 07/19 /2020 (bbb) Patient #21059 - Type and Screen performed on 07/24/2020 (ccc) Patient #25103 - Crossmatch performed on 07/29/2020 (ddd) Patient #17921 - Crossmatch performed on 07/29/2020
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On 09/24/2020 at 1:00 pm, technical consultant #2 stated to surveyor #1 Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, CK (Creatine Kinase), Chloride, Sodium, Creatinine, Glucose, Lipase, Magnesium, Phosphorus, Total Protein, HDL (High Density Lipoprotein), Total Cholesterol, Triglyceride, Lactate, GGT (Gamma-Glutamyl Tranferase), LD (Lactate Dehydrogenase), CRP (C-Reactive Protein), Alcohol, Transferrin, Uric Acid, Iron, Ammonia, and Salicylate testing were performed using the Beckman Coulter Unicel SXC 600i analyzer; (2) Surveyor #1 reviewed 2020 calibration records and identified that calibration procedures for the above analytes had been performed with one or two levels of calibrators. Since the calibration procedures included only one level, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) Surveyor #1 reviewed calibration verification records performed from November 2018 through the current date and identified that calibration verification had not been performed as follows: (a) Alcohol - During the review period of 11/05/2018 to date (b) Ammonia - During the review period of 11/05/2018 to date (c) Iron - After - During the review period of 11/05/2018 to date (d) Magnesium - Between 11/05/2018 and 12/30/2019, and after 12/30/2019 (e) Uric Acid - After 11/05/2018 (f) Albumin, Alkaline Phosphatase, ALT, Amylase AST, BUN, CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, CK, Chloride, Sodium, Creatinine, Glucose, Lipase, Phosphorus, Total Protein, HDL, Total Cholesterol, Triglyceride, Lactate, GGT, LD, CRP, Transferrin, and Salicylate - After 12/30/2019 (4) Surveyor #1 reviewed the records with technical consultant #2 and asked if there were additional records to prove calibration verification had been performed every 6 months. Technical consultant #2 stated to surveyor #1 on 09/24/2020 pm at 3:20 pm calibration verification procedures had not been performed as required; (5) The following are examples of patient CMP* testing performed when calibration verification had not been performed: (a) Patient

	#52335 - Testing performed on 06/30/2020 (b) Patient #225964 - Testing performed on 07/01/2020 *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Hematology, Coagulation, and Chemistry testing for 8 of 8 months. Findings include: HEMATOLOGY (1) On 09/21/2020 at 11:50 am, technical consultant #2 stated the following to surveyor #2: (a) CBC (Complete Blood Count) testing was performed using the Beckman Coulter DXH 800 analyzer: (b) Three levels of QC (quality control) materials were performed each day of patient testing. (2) On 09/23/2020 surveyor #2 requested QC records (i.e., Levey-Jennings data) for the above testing performed from January 2020 through August 2020 to ensure QC had been monitored for variances. Technical consultant #2 stated on 09/23/2020 at 02:10 pm there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period; (3) The following are examples of patient CBC testing performed when control results had not been monitored for shifts and trends: (a) Patient #23356 - Testing performed on 01/22/2020 (b) Patient #33816 - Testing performed on 01/29/2020 (c) Patient #210355 - Testing performed on 01/30/2020 (d) Patient #27125 - Testing performed on 02/26/2020 (e) Patient #14491 - Testing performed on 02/27/2020 (f) Patient #32114 - Testing performed on 03/30/2020 (g) Patient #212181 - Testing performed on 03/31/2020 (h) Patient #34606 - Testing performed on 04/30/2020 (i) Patient #68564 - Testing performed on 05/29/2020 (j) Patient #20060 - Testing performed on 05/29/2020 (k) Patient #52335 - Testing performed on 06/30/2020 (l) Patient #225964 - Testing performed on 07/01/2020 COAGULATION (1) On 09/21/2020 at 11:57 am, technical consultant #2 stated the following to surveyor #2: (a) PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time), and D-dimer testing were performed using the IL ACL TOP analyzer: (b) Two levels of QC materials were performed each eight hours of patient testing. (2) On 09/23/2020 surveyor #2 requested QC records (i. e., Levey-Jennings data) for the above testing performed from January 2020 through August 2020 to ensure QC had been monitored for variances. Technical consultant #2 stated on 09/23/2020 at 02:30 pm there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period; (3) The following are examples of patient PT/INR testing performed when control

	results had not been monitored for shifts and trends: (a) Patient #13734 - Testing performed on 01/30/2020 (b) Patient #34863 - Testing performed on 02/21/2020 (c) Patient #4184 - Testing performed on 02/25/2020 (d) Patient #57067 - Testing performed on 02/27/2020 (e) Patient #60971 - Testing performed on 03/26/2020 (f) Patient #4184 - Testing performed on 03/31/2020 (g) Patient #1492 - Testing performed on 04/29/2020 (h) Patient #57625 - Testing performed on 04/30/2020 (i) Patient #23122 - Testing performed on 05/22/2020 (j) Patient #20841 - Testing performed on 05/26/2020 (k) Patient #60971 - Testing performed on 05/28/2020 (l) Patient #13734 - Testing performed on 06/25/2020 (m) Patient #22209 - Testing performed on 06/30/2020 (n) Patient #4184 - Testing performed on 07/07/2020 CHEMISTRY (1) On 09/24/2020 at 1:00 pm, general supervisor/technical consultant #1 stated the following to surveyor #1: (a) Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, CK (Creatine Kinase), Chloride, Sodium, Creatinine, Glucose, Lipase, Magnesium, Phosphorus, Total Protein, HDL (High Density Lipoprotein), Total Cholesterol, Triglyceride, Lactate, GGT (Gamma-Glutamyl Tranferase), LD (Lactate Dehydrogenase), CRP (C-Reactive Protein), Alcohol, Transferrin, Uric Acid, Iron, Ammonia, and Salicylate testing were performed using the Beckman Coulter Unicel SXC 600i analyzer; (b) Two levels of QC materials were performed each day of patient testing. (2) Surveyor #1 requested QC records (i.e., Levey-Jennings data) for the above testing performed from January 2020 through August 2020 to ensure QC had been monitored for variances. The general supervisor/technical consultant #1 stated on 09/24/2020 at 3:40 pm there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period; (3) The following are examples of patient CMP* testing performed when control results had not been monitored for shifts and trends: (a) Patient #23356 - Testing performed on 01/22/2020 (b) Patient #33816 - Testing performed on 01/29/2020 (c) Patient #210355 - Testing performed on 01/30/2020 (d) Patient #27125 - Testing performed on 02/26/2020 (e) Patient #14491 - Testing performed on 02/27/2020 (f) Patient #32114 - Testing performed on 03/30/2020 (g) Patient #212181 - Testing performed on 03/31/2020 (h) Patient #34606 - Testing performed on 04/30/2020 (i) Patient #68564 - Testing performed on 05/29/2020 (j) Patient #20060 - Testing performed on 05/29/2020 (k) Patient #52335 - Testing performed on 06/30/2020 (l) Patient #225964 - Testing performed on 07/01/2020 *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical

	consultant #1 and technical consultant #2, the laboratory failed to perform quality control as stated in the IQCP for Clostridium difficile testing. Findings include: (1) On 09/21/2021 at 11:25 am, the general supervisor/technical consultant #1 and technical consultant #2 stated the following to the surveyor: (a) The laboratory performed Clostridium difficile testing using the Quidel Solona kit; (i) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (ii) The results for two levels of control materials must be acceptable in order to report patient results. (2) Surveyor #2 reviewed Clostridium difficile quality control records for testing performed from January 2019 through August 2020. For the review period, the following was identified for 2 of 20 months: (a) Monthly quality control results could not be located for the following: (i) Between 01/07/2019 and 04/17/2019 (3) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2, the technical consultant #2 stated on 09/23/2021 at 03:17 pm quality control had not been performed as stated in the IQCP.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory failed to provide evidence a negative and positive control material had been performed each day of patient Immunohematology testing. Findings include: (1) On 09/21/2021 at 11:45, technical consultant #2 stated to surveyor #2 the laboratory performed ABO/Rh Type, Antibody Screen, and Compatibility testing using the Ortho ID MTS Gel system; (2) On 09/24 /2021, surveyor #2 reviewed Immunohematology records for testing performed during 01/09/2020 through 07/29/2020. There was no evidence quality control testing had been performed for 51 of 51 days when patient Type and Screen Testing (consisted of ABO/Rh and Antibody Screen) and Crossmatch Testing (consisted of ABO/Rh, Antibody Screen, and Compatibility testing) as follows: (a) Patient #228712- ABO/Rh type performed on 01/09/2020 ; (b) Patient #224992- Crossmatch performed on 01/10 /2021; (c) Patient #1817 - Type and Screen performed on 01/13/2020; (d) Patient #1773 - Crossmatch performed on 01/15/2020; (e) Patient #3442 - Crossmatch performed on 01/18/2020; (f) Patient #1817 - Crossmatch performed on 01/24/2020; (g) Patient #80027 - Crossmatch performed on 01/26/2020; (h) Patient #228906 - Type and Screen performed on 01/27/2020; (i) Patient #210543 - Crossmatch performed on 01/27/2020; (j) Patient #228968 - Crossmatch performed on 02/01 /2020; (k) Patient #226671 - Crossmatch performed on 02/02/2020; (l) Patient #228967 - Crossmatch performed on 02/03/2020; (m) Patient #228207 - Type and Screen performed on 02/06/2020; (n) Patient #228967 - Crossmatch performed on 02 /20/2020; (o) Patient #205928 - Crossmatch performed on 02/20/2020; (p) Patient #229211 - ABO/Rh type performed on 02/22/2020; (q) Patient #2912 - Type and Screen performed on 02/24/2020; (r) Patient #8636 - Crossmatch performed on 02/28 /2020; (s) Patient #1046082 - Crossmatch performed on 02/29/2020; (t) Patient #211513 - Crossmatch performed on 03/02/2020; (u) Patient #215103 - Crossmatch

	performed on 03/06/2020; (v) Patient #17743 - Crossmatch performed on 03/11/2020; (w) Patient #25006 - Crossmatch performed on 03/16/2020; (x) Patient #229544 - Crossmatch performed on 03/27/2020; (y) Patient #26735 - Crossmatch performed on 04/03/2020; (z) Patient #19753 - ABO/Rh type performed on 04/04/2020; (aa) Patient #17743 - Crossmatch performed on 04/06/2020; (bb) Patient #217147 - ABO/Rh type performed on 04/08/2020; (cc) Patient #16063 - Crossmatch performed on 04/14 /2020; (dd) Patient #25103 - Crossmatch performed on 04/18/2020; (ee) Patient #80027 - Crossmatch performed on 04/21/2020; (ff) Patient #35248 - Antibody screen performed on 04/27/2020; (gg) Patient #229709 - Crossmatch performed on 04/28 /2020; (hh) Patient #43938 - Crossmatch performed on 05/02/2020; (ii) Patient #47231 -Type and Screen performed on 05/05/2020; (jj) Patient #41626 - Type and Screen performed on 05/07/2020; (kk) Patient #21059 - Crossmatch performed on 05 /28/2020; (ll) Patient #22059 - Crossmatch performed on 06/03/2020; (mm) Patient #17743 - Crossmatch performed on 06/17/2020; (nn) Patient #28112 - Type and Screen performe on 06/18/2020; (oo) Patient #7967 - Crossmatch performed on 06/18 /2020; (pp) Patient #74333 - Crossmatch performed on 06/22/2020; (qq) Patient #91692 - Crossmatch performed on 06/24/2020; (rr) Patient #227906 - ABO/Rh performed on 06/27/2020; (ss) Patient #29464 - Crossmatch performed on 07/01 /2020; (tt) Patient #66571 - Crossmatch performed on 07/09/2020; (uu) Patient #25103 - Crossmatch performed on 07/10/2020; (vv) Patient #34880 - Crossmatch performed on 07/14/2020; (ww) Patient #17743 - Crossmatch performed on 07/15 /2020; (xx) Patient #45029 - Crossmatch performed on 07/16/2020; (yy) Patient #227379 - Crossmatch performed on 07/19/2020; (zz) Patient #21059 - Type and Screen performed on 07/24/2020; (aaa) Patient #25103 - Crossmatch performed on 07 /29/2020; (bbb) Patient #17921 - Crossmatch performed on 07/29/2020. (3) The surveyor reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2, the general supervisor/technical consultant #1 and technical consultant stated on 09/24/2021 at 03:35 pm there was no evidence quality control testing had been performed as indicated above.
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 a review of records, observation, and interview with technical consultant #2, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: ALARM CHECKS (1) On 09/21/2020 at 11:45, technical consultant #2 stated to surveyor #2 units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 09/23/2020, a procedure for performing alarm checks on the blood bank refrigerator could not be located (refer to D5401). Technical consultant #2 stated to surveyor #2 on 09/23/2020 at 2:30 pm, the low and high refrigerator alarm checks were to be performed quarterly (Note: units of packed cells must be stored at 1-6 degrees Centigrade). (3) Surveyor #2 reviewed records for 2019 and 2020. There was no evidence alarm checks had been performed after 12/31/2019; (4) Surveyor #2

	reviewed the findings with technical consultant #2 who stated on 09/23/2020 at 3:00 pm, there was no documentation to prove alarm checks had been performed in 2020. THERMOGRAPH CHARTS (1) On 09/21/2020 at 12:00 pm, surveyor #1 observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts. Each chart monitored the temperature for a 7 day period; (2) On 09/23/2020 surveyor #2 requested refrigerator charts from 12/30/2019 through the current date. Technical consultant #2 stated to surveyor #2 on 09/23/2020 at 10:30 am that refrigerator charts were not available from 12/30/2019 through 08/12/2020; (3) Since the refrigerator charts were not available for review, surveyor #2 could not substantiate that units of packed red blood cells had been stored under appropriate conditions and continuously monitored over a 24-hour period.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have written procedures for Blood Bank testing and Blood Gas Testing. Refer to D5401; (b) The laboratory failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (c) The laboratory failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (d) The laboratory failed to ensure the the performance specifications of a new test system were approved by the laboratory. Refer to D5421; (e) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (f) The laboratory failed to perform function checks on the blood bank centrifuge as required by the manufacturer. Refer to D5431; (g) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (h) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Hematology, Coagulation, and Chemistry testing. Refer to D5441; (i) The laboratory failed to perform quality control as stated in the IQCP for Clostridium difficile testing. Refer to D5445; (j) The laboratory failed provide evidence a negative and positive control material had been performed each day of patient Immunohematology testing. Refer to D5449; (k) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555. 39088 Based on a review of records and interview with the general supervisor /technical consultant #1 and technical consultant #2, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 09/21 /2020 at 11:010 am, technical consultant stated the following to the surveyor: (a) The laboratory performed the following tests on the Alere Triage Analyzer: (i) D-Dimer; (ii) CKMB (iii) Urine Drug Screen (b) An IQCP (Individualized Quality Control Plan)

	had been developed for each test system. (2) Surveyor #2 reviewed the IQCP (dated as approved on 01/07/2016). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. The technical consultant #2 stated on 09/23/2020 at 10:02:45 pm, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported.Refer to D6014; (3) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Refer to D6016; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the reportable ranges had been verified for a new test method; and failed to

	ensure the the performance specifications of a new test system were approved by the laboratory. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2 , the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) The laboratory director or designee failed to sign proficiency testing attestation statements for 2 of 32 events. Refer to D2015.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory verified the accuracy of Cerebral Spinal Fluid manual cell counts at least twice annually. Refer to D5217; (2) The laboratory director failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process for Hematology, Coagulation, and Chemistry testing. Refer to D5441; (3) The laboratory director failed to ensure quality control had been performed as stated in the IQCP for Clostridium difficile testing. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment; and failed to ensure the laboratory had a policy for monitoring the effectiveness of their IQCP. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with general supervisor/technical consultant #1 and technical consultant #2 the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Findings include: (1) The laboratory director failed to ensure a the laboratory had a written competency policy for the technical consultant based on the job responsibilities as listed in Subpart M. Refer to D5209; (2) The laboratory director failed to ensure the laboratory had complete written policies and procedures for Blood Gas testing. Refer to D5401; (3) The

	laboratory director failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Refer to D5407.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (2) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (3) The technical consultant failed to ensure that evaluations included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. Refer to D6047; (4) The technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Refer to D6053; (5) The technical consultant failed to ensure evaluations included all moderate complexity testing performed. Refer to D6053.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical consultant failed to ensure the reportable ranges had been verified for a new test method; and failed to ensure the the performance specifications of a new test system were approved by the laboratory. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by:

	Based on a review of records, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (2) The technical consultant failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The technical consultant failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439; (4) The technical consultant failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process for Hematology, Coagulation, and Chemistry testing. Refer to D5441; (5) The technical consultant failed to ensure quality control had been performed as stated in the IQCP for Clostridium difficile testing. Refer to D5445.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor/technical consultant #1 and technical consultant #2, the technical consultant failed to ensure that evaluations included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. Findings include: (1) On 09/21/2020 at 11:15 am, the laboratory manager stated the following to surveyor #2: (a) Routine CBC (Complete Blood Count) testing was performed using the Beckman Coulter Unicel DxH 800 Coulter analyzer; (b) Routine Chemistry testing was performed Unicel DxC 600i analyzer. (2) Surveyor #2 reviewed personnel records for 2 persons performing the testing as indicated above, who had evaluations performed in 2019. For 2 of 2 persons, there was no evidence that direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was performed on 08/01 /2019; (b) Testing Person #2 - The evaluation form was completed on 12/19/2019. (3) The findings were discussed with the general supervisor/technical consultant #1 and technical consultant #2 who stated on 09/21/2020 at 02:35 pm there was no documentation to prove the evaluations above included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical

	consultant #1 and technical consultant #2, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 1 of 1 testing persons. Findings include: (1) On 09 /21/2020, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #2 - The initial training for this person was completed on 6/13/2018. There was no evidence that a semiannual evaluation had been performed (due 12 /2018); (2) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2 who stated on 09/21/2020 at 02:00 pm there were no records to prove the above person had been evaluated semiannually.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 2 of 2 testing persons. Findings include: (1) On 09/21/2020 at 11:00 am, the technical consultant #2 stated the following to surveyor #2: (a) RF (Rheumatoid Factor) test was performed using the Cardinal Health RF Latex test; (b) Serum hCG (Human Chorionic Gonadotropin) was performed using the Quidel Quickue+ One Step hCG test; (c) Urine Drug Screen (Amphetamines, Barbiturates, Benzodiazepine, Cannabinoids, Cocaine Metabolite, Opiates) were performed on the Alere Triage analyzer; (d) Post Vasectomy semen examinations (present/absense); (2) Surveyor #2 then reviewed personnel records for 2 persons performing the above test procedures in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 08/01/2019 (b) Testing Person #2 - Performed on 12 /19/2019 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of RF, Serum hCG, Urine Drug Screen and Post Vasectomy semen examination testing; (4) Surveyor #2 reviewed the findings with general supervisor/technical consultant #1 and technical consultant #2, who both stated on 09 /21/2020 at 02:30 pm the above evaluations did not include the test procedures as indicated above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, policies and procedures, and interview with technical consultant #2 and the general supervisor/technical consultant #1, the laboratory director failed to provide overall management and direction for high complexity testing. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to

	ensure accurate and reliable results were reported. Refer to D6087; (2) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6094; (4) The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D6095; (5) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2 and the general supervisor/technical consultant #1, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory performed function checks on the blood bank centrifuge as required by the manufacturer. Refer to D5431.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records and interview with the the general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory could provide evidence a negative and positive control material had been performed each day of patient Immunohematology testing. Refer to D5449.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, policies and procedures, and interview with technical consultant #2 and the general supervisor/technical consultant #1, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory

	director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with technical consultant #2, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Findings include: (1) The laboratory director failed to ensure units of blood were stored under appropriate conditions. Refer to D5555.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with general supervisor/technical consultant #1 and technical consultant #2, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings include: (1) The laboratory director failed to ensure a the laboratory had a written competency policy for the general supervisor based on the job responsibilities as listed in Subpart M. Refer to D5209; (2) The laboratory director failed to ensure complete written procedures were available for performing Blood Bank testing. Refer to D5401.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical supervisor failed to provide technical supervision in accordance with 493. 1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure a quality control program was maintained to ensure the to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6117; (2) The technical supervisor failed to ensure that evaluations included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. Refer to 6121; (3) The technical supervisor failed to ensure that a person performing high complexity testing had been evaluated semiannually

	during the first year of testing for 1 of 1 testing persons. Refer to D6127; (4) The technical supervisor failed to ensure evaluations included all high complexity testing performed for 2 of 2 testing persons. Refer to D6128.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical supervisor failed to ensure a quality control program was maintained to ensure the to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the accuracy of Cerebral Spinal Fluid manual cell counts had been verified at least twice annually. Refer to D5217; (2) The technical supervisor failed to ensure function checks were performed on the blood bank centrifuge as required by the manufacturer Refer to D5431; (3) The technical supervisor failed to ensure the laboratory could provide evidence a negative and positive control material had been performed each day of patient Immunohematology testing. Refer to D5449; (4) The technical supervisor failed to ensure units of blood were stored under appropriate conditions. Refer to D5555.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical supervisor failed to ensure that evaluations included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing. Findings include: (1) On 09/21/2020 at 11:10 am, technical consultant #2 stated Crossmatching (ABO/Rh type, Antibody Screen, and Compatibility) testing were performed using the Ortho ID-MTS Gel System method; (2) Surveyor #2 reviewed personnel records for 2 persons performing Crossmatching testing, who had evaluations performed in 2019. For 2 of 2 persons, there was no evidence that direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was performed on 08/01/2019; (b) Testing Person #2 - The evaluation form was completed on 12/19/2019. (3) The findings were discussed with the general supervisor/technical consultant #1 and technical consultant #2 who stated on 09/21/2020 at 02:35 pm there was no documentation to prove the

	evaluations above included direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing.
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 a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical supervisor failed to ensure that a person performing high complexity testing had been evaluated semiannually during the first year of testing for 1 of 1 testing persons. Findings include: (1) On 09 /21/2020, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #2 - The initial training for this person was completed on 6/13/2018. There was no evidence that a semiannual evaluation had been performed (due 12 /2018); (2) Surveyor #2 reviewed the records with the general supervisor/technical consultant #1 and technical consultant #2 who stated on 09/21/2020 at 02:00 pm there were no records to prove the above person had been evaluated semiannually.
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 a review of records and interview with the general supervisor/technical consultant #1 and technical consultant #2, the technical supervisor failed to ensure evaluations included all high complexity testing performed for 2 of 2 testing persons. Findings include: (1) On 09/21/2020 at 11:00 am, the technical consultant #2 stated the following to surveyor #2: (a) Gram Stain - CSF (Cerebral Spinal Fluid) and Body Fluids. (2) Surveyor #2 then reviewed personnel records for 2 persons performing the above test procedure in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 08/01/2019 (b) Testing Person #2 - Performed on 12/19/2019 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of Gram Stain; (4) Surveyor #2 reviewed the findings with general supervisor/technical consultant #1 and technical consultant #2, who both stated on 09/21/2020 at 02:30 pm the above evaluations did not include the test procedure as indicated above.