Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2088219	10/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp Oklahoma, Inc Cityplex	2408 E 81st St, Ste 105, Tulsa, 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 10/26,27,28/2020. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director, laboratory manager, director of laboratory operations, laboratory support MLS, and laboratory lead during an exit conference performed 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 laboratory manager, the laboratory director or designee failed to sign proficiency testing attestation statements for 1 of 13 events. Findings include: (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following for 1 of 13 events: (a) First 2019 Chemistry Core Event- The attestation statement had not been signed by the laboratory director or designee. (2) Surveyor #2 reviewed the findings with the laboratory manager who stated on 10/27/2020 at 02:50 pm, the attestation statement had not been signed by the laboratory director or designee as indicated above.

D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to take remedial action for unacceptable proficiency testing scores. Findings include: (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following was identified: (a) First 2019 Chemistry Core Event (i) Sodium - The laboratory received a score of 40%. The results for samples CH-01, CH-04, and CH-05 had failed. There was no documentation to prove that remedial action had been taken. (2) Surveyor #2 reviewed the records with the laboratory manager and asked if remedial action had been taken for the failures. The laboratory manager reviewed the records and stated on 10/27/2020 at 02:55 pm there was no evidence that remedial action had been taken.
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 laboratory manager, the laboratory failed to have a written technical supervisor and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 10/26/2020, surveyor #2 reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence competencies had been performed for the technical supervisor and general supervisor based on their job responsibilities; (2) Surveyor #2 asked the laboratory manager if a written policy to evaluate the technical supervisor and general supervisor, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory manager stated to surveyor #2 on 10/28/2020 at 04:30 pm, a policy to evaluate the technical supervisor and general supervisor based on job responsibilities had not been written; and competencies had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for 2 of 13 events. Findings include: FAILURES (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following failures: (a) First 2019 Chemistry Core Event (i) CO2 - The laboratory failed the results for 3 of 5 samples (CH-01, CH-03, CH-05); (ii) Total Protein - The laboratory failed the results for 1 of 5 samples (CH-02) (b) Second 2020 Chemistry Core Event (i) TCO2 - The laboratory failed the results for 1 of 5 samples (IB-09) (2) The records were then reviewed further by the surveyor. There was no evidence corrective action had been taken for the above failures; (3) Surveyor #2 reviewed the records with the laboratory manager, and asked if corrective actions had been taken and documented for the failures. The labortory manager stated on 10/27/2020 at 02:30 pm corrective actions had not been taken. BIASES (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2019 Chemistry Core Event (i) Potassium - 5 of 5 results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.0 (bb) Sample CH-02 - SDI of 2.3 (cc) Sample CH-03 - SDI of 2.0 (dd) Sample CH-04 - SDI of 2.8 (ee) Sample CH-05 - SDI of 4.2 (ii) Ionized Calcium - 3 of 5 results exhibited a positive bias (aa) Sample IB-02- SDI of 2.4 (bb) Sample IB-03 - SDI of 2.5 (cc) Sample IB-05 - SDI of 2.2 (b) Second 2019 Chemistry Core Event (i) Glucose - 3 of 5 results exhibited a negative bias (aa) Sample CH-07 - SDI of -2.5 (bb) Sample CH-08 - SDI of -2.1 (cc) Sample CH-09 - SDI of -2.4 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 10/27/2020 at 02:35 pm the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 2 of 13 events. Findings include: (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 First Event - Urine Sediment sample US-02 (b) Hematology (i) 2020 Second Event - Blood Cell Identification ECI-06 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) Surveyor #2 asked the laboratory manager if the results had been documented as evaluated. The laboratory manager reviewed the records and stated on 10/27/2021 at 12:45 pm the non-graded results had not been documented as reviewed.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory manager, director of laboratory operations, laboratory lead, and laboratory support and quality management technologist, the laboratory failed to have complete written policies and procedures for 2 of 2 test systems. Findings include: ACT TESTING ON HEMACHRON SIGNATURE ELITE (1) On 10/26/2020 at 09:45 am, the laboratory manager and director of laboratory operations stated to surveyor #1 ACT (Activated Clotting Time) testing was performed at the point of care in the Cath Lab using the Hemachron Signature Elite analyzer; (2) On 10/27/2020, surveyor #1 reviewed the procedure titled, "Hemochron Procedure". The quality control procedures did not include the following: (a) Frequency of testing controls; (b) Establishing quality control limits; (c) Criteria to determine acceptable control results. (3) Surveyor #1 reviewed the findings with the laboratory lead and the laboratory support and quality management technologist and asked if the procedures were available. Both stated on 01/27/2020 at 03:33 pm the procedures had not been written. TROPONIN I TESTING ON SIEMENS STRATUS (1) On 10/26/2020 at 09:50 am, the laboratory manager and director of laboratory operations stated to surveyor #1 Troponin I testing was performed using the Siemens Stratus analyzer as the primary method; (2) On 10/27/2020, surveyor #1 reviewed the procedure titled, "Troponin I". The quality control procedures did not include the following: (a) Identity (e.g., normal, abnormal, level I,II) (b) Establishing quality control limits; (c) Criteria to determine acceptable control results; (d) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (3) Surveyor #1 reviewed the findings with the laboratory lead and the laboratory support and quality management technologist and asked if the procedures were available. Both stated on 01/28/2020 at 11:22 am the procedures had not been written.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for Coagulation for 1 of 1 reagent lot changes. Findings include: (1) On 10/26/2020 at 10: 00 am, the laboratory manager stated the following to surveyor #2: (a) The IL ACL Top analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing and PTT (Partial Thromboplastin Time) testing; (i) Hemosil Rediplastin PT Reagent Lot# N0278177 was put into use 09/02/2020' (ii) Synthasil PTT Reagent Lot#N1081481 was put into use 02/2020 (the exact date could not be determined by the laboratory. (2) The surveyor reviewed the manufacturer's Hemostasis Performance Verification Manual instructions for "COMPARISON STUDY", which stated: (a) "4. At least 50% of the samples should be outside of the laboratory normal reference interval, if possible." (b) "5. At least 40 specimens should be analyzed. More samples will improve the confidence in the data." (3) Surveyor #2 reviewed the documentation for the reagent lot changes, but could not locate the comparison study for the above reagents. The laboratory manager stated on 10/28 /2020 at 11:30 am the documentation to prove the comparison studies had been performed could not be located.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager and director of laboratory operations, the laboratory failed to ensure materials were stored as required for 8 of 9 months. Findings include: (1) On 10/26/2020 at 10:00 am, surveyor #1 observed the contents of the Frigidaire freezer, denoted by the laboratory as freezer #1 and the General Electric freezer, denoted by the laboratory as freezer #2. Both of the freezers were frost-free freezers. The following control materials were being stored in the freezers, along with the manufacturer's storage requirements: (a) Freezer #1 - Bio-Rad Liquicheck Cardiac Markers Plus controls - 6 plastic tubes containing 200 ul (microliter) aliquots of level 1 (lot #87811), 8 plastic tubes containing 200 ul aliquots of level 2 (lot #29882), and 11 plastic tubes containing 200 ul aliquots of level 3 (lot #87813); the storage requirement was -20 to -70 degrees Centigrade (C). In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer"; (b) Freezer #2 - Bio-Rad Liquid Assayed Multiqual controls - 2 bottles of level 1 (lot #45831), 2 bottles of level 3 (lot #45833), 8 boxes containing 12 bottles each of level 1 (lot #45871), and 8 boxes containing 12 bottles each of level 3 (lot #45873); the storage requirement was -20 to -70 degrees

	Centigrade (C). In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer". (2) On 10/26/2020 at 10:30 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) The Bio-Rad Liquicheck Cardiac Markers Plus controls (level 1 and level 3) were used to perform quality control procedures, and level 2 was used as an additional control material following calibration procedures for Troponin I testing performed on the Siemens Status analyzer; (b) The Bio-Rad Liquid Assayed Multiqual controls were used to perform quality control procedures for 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, and Triglyceride testing performed on the Beckman Coulter AU480 analyzer. (3) On 10/27/2020, surveyor #1 reviewed temperature records for 9 months (January through September 2020). In addition to the freezers being frost-free, the documented temperatures were warmer than -20 C (the warmest temperature allowed for the materials) during 6 of 9 months for freezer #1 and 8 of 9 months for freezer #2 as follows: (a) Freezer #1 (i) January - 5 of 31 documented temperatures were warmer than -20 degrees C (ii) April - 3 of 30 documented temperatures were warmer than -20 degrees C (iii) May - 14 of 31 documented temperatures were warmer than -20 degrees C (iv) June - 14 of 30 documented temperatures were warmer than -20 degrees C (v) July - 25 of 31 documented temperatures were warmer than -20 degrees C (vi) August - 21 of 31 documented temperatures were warmer than -20 degrees C (b) Freezer #2 (i) January - 4 of 31 documented temperatures were warmer than -20 degrees C (ii) March - 2 of 31 documented temperatures were warmer than -20 degrees C (iii) April - 21 of 30 documented temperatures were warmer than -20 degrees C (iv) May - 14 of 31 documented temperatures were warmer than -20 degrees C (v) June - 22 of 30 documented temperatures were warmer than -20 degrees C (vi) July - 30 of 31 documented temperatures were warmer than -20 degrees C (vii) August - 11 of 31 documented temperatures were warmer than -20 degrees C (viii) September - 20 of 30 documented temperatures were warmer than -20 degrees C (4) Surveyor #1 reviewed the records with the laboratory manager and director of laboratory operations. Both stated on 10/27/2020 at 11:40 am, they were not aware the manufacturer did not allow storage of the materials in a frost-free freezer, and the freezer temperatures were unacceptable as shown above. 39088 Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required for 2 of 4 months. Findings include: (1) On 10/26/2020 at 09:55 am, the laboratory manager stated to surveyor #1 Antibody Screen testing was performed in the laboratory using the Ortho ID-MTS gel system; (2) The surveyor then reviewed the manufacturer's environmental requirements for the Ortho ID-MTS gel card. The manufacturer required the room temperature to be maintained within the range of 2-25C or (35.6 - 77 F); (3) Surveyor #2 reviewed laboratory records from June 2020 through September 2020 and identified days where the room temperature was greater than 25C or 77 F as follows: (a) June 2020 (i) 06/14/2020 the temperature was documented as 79.2F (ii) 05/15/2020 the temperature was documented as 78.3F (iii) 06 /19/2020 the temperature was documented as 78.7F (iv) 06/20/2020 the temperature was documented as 79.6F (v) 06/21/2020 the temperature was documented as 79.6F (vi) 06/28/2020 the temperature was documented as 80.1F (b) September 2020 (i) 09 /05/2020 the temperature was documented as 77.9F (ii) 09/06/2020 the temperature was documented as 79.5F (4) Surveyor #2 reviewed the records with the laboratory manager. The laboratory manager stated on 10/28/2020 at 10:30 am, the laboratory failed to store the Ortho ID-MTS gel card as required by the manufacturer.

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 a review of records and interview with the laboratory manager, the laboratory failed to ensure reagents had not exceeded their expiration date for 1 of 28 days. Findings include: (1) On 10/26/2020 at 09:55 am, the laboratory manager stated to surveyor #1 Crossmatch testing was performed in the laboratory which included: (a) ABO/Rh Typing using the tube method (b) Antibody Screen testing using the Ortho ID-MTS gel system (2) On 10/28/2020, surveyor #2 reviewed quality control (QC) and patient testing records for February 2019. It was identified that expired ORTHO Confidence Cell A1B (used for ABO typing) had been used for 1 of 28 days reviewed: (a) ORTHO Confidence lot #A186, expiration date of 02/26/2019 had been used to perform QC on 02/27/2019. (3) Surveyor #2 reviewed the records with the laboratory manager who stated on 10/28/2020 at 10:45 am the expired reagent had been used 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 laboratory manager, director of laboratory operations, and laboratory support and quality management technologist, the laboratory failed to perform monthly maintenance procedures as required by the manufacturer. Findings include: (1) On 10 /26/2020 at 09:50 am, the laboratory manager and director of laboratory operations stated to surveyor #1 Troponin I testing was performed using the Siemens Stratus analyzer as the primary method; (2) On 10/27/2020, surveyor #1 reviewed the manufacturer's monthly maintenance instructions, as stated on the maintenance log, which were: (a) Clean Air Filter (b) Clean Instrument Surfaces: Sample Door Area Lower Cannuala Chamber Seal Waste Container Area Tip Chute Pak Shield (3) Maintenance records were reviewed by surveyor #1 from January 2020 to date. The monthly maintenance had not been documented as performed since 06/02/2020: (4) Surveyor #1 reviewed the records with the laboratory support and quality management technologist, who stated on 10/27/2020 at 3:36 pm, there was no evidence the monthly maintenance had been performed as required.
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 the laboratory manager and director of laboratory operations, the laboratory failed to perform calibration verification procedures at least once every 6 months for 2 of 2 analyzers. Findings include:
SIEMENS STRATUS ANALYZER (1) On 10/26/2020 at 09:45 am, the laboratory manager and director of laboratory operations stated to surveyor #1 Troponin I testing was performed using the Siemens Stratus analyzer as the primary method; (2) On 10 /28/2020, surveyor #1 reviewed 2020 calibration records and identified that calibration procedures for Troponin I had been performed with one level of calibrator. 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 since the installation of the analyzer on 03 /18/2018, and identified that calibration verification had not been performed as follows: (a) Between 03/18/2018 and 01/12/2020 (b) Between 01/12/2020 and 10/14 /2020 (4) Surveyor #1 reviewed the records with the laboratory manager and asked if there were additional records to prove calibration verification had been performed every 6 months. The laboratory manager stated to surveyor #1 on 10/28/2020 at 2:05 pm calibration verification procedures had not been performed as required.
BECKMAN COULTER AU480 ANALYZER (1) On 10/26/2020 at 09:50 am, the laboratory manager and director of laboratory operations 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, and Triglyceride testing were performed using the Beckman Coulter AU480 analyzer; (2) On 10/28/2020, 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 August 2018 through the current date and identified that calibration verification had not been performed as follows: (a) Albumin - Between 08/22/2018 and 08/29/2019 (b) Alkaline Phosphatase, ALT, Amylase,

	AST, CK, CO2, Lipase, and Total Protein - Between 08/01/2018 and 08/29/2019 (c) BUN - Between 07/31/2018 and 08/30/2019 (d) Calcium, Cholesterol, Chloride, Creatinine, Direct Bilirubin, Potassium, Glucose, HDL, Total Bilirubin, Phosphorus, Sodium, and Magnesium - Between 08/01/2018 and 08/29/2019 (4) Surveyor #1 reviewed the records with the laboratory manager and asked if there were additional records to prove calibration verification had been performed every 6 months. The laboratory manager stated to surveyor #1 on 10/28/2020 at 2:40 pm calibration verification procedures had not been performed as required.
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 laboratory manager, director of laboratory operations, and the laboratory lead, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process. Findings include: TROPONIN I (1) On 10/26/2020 at 09:50 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) Troponin I testing was performed using the Siemens Stratus analyzer as the primary method; (b) Two levels of Bio-Rad Liquichek Cardiac Markers Plus controls (level 1 and level 3) were performed each day of patient testing. (2) On 10/28/2020, surveyor #1 reviewed quality control records for 4 lot numbers of control materials used from 01/07/2020 through the current date. For 4 of 4 lot numbers, there were there were no records (i. e., Levey-Jennings data) proving the control results had been monitored for variances: (a) Level 1 lot #29881 and Level 3 lot #29883 - Used from 01/07/2020 through 09/16 /2020; (b) Level 1 lot #87811 and level 3 lot #87813 - Put into use on 10/06/2020 and was currently in use. (3) Surveyor #1 asked the laboratory lead if the lot numbers above had been monitored for variances. The laboratory lead stated to surveyor #1 on 10/28/2020 at 11:23 am, the controls were not routinely monitored for variances. HEMATOLOGY (1) On 10/26/2020 at 09:55 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XN-1000 analyzer; (b) Three levels of Sysmex XN Check controls (level 1, level 2, and level 3) were performed each day of patient testing; (c) The laboratory established their own means and ranges before new lot numbers of quality control materials were put into use. (2) On 10/28 /2020, surveyor #1 reviewed quality control records for 15 lot numbers used from 11 /13/2019 through 09/13/2020. For 15 of 15 lot numbers, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances using the laboratory's established ranges for each analyte tested (e.g., White Blood Cell, Hemoglobin, Platelet, etc.). The records only included data from the Sysmex Insight peer group reports and the lot numbers were: (a) Level 1 lot #93181101, level

	2 lot #93181102, and level 3 lot #93181103 - Used form 11/13/2019 through 02/02 /2020; (b) Level 1 lot #00091101, level 2 lot #00091102, and level 3 lot #00091103 - Used from 01/08/2020 though 03/29/2020; (c) Level 1 lot #00651101, level 2 lot #00651102, and level 3 lot #00651103 - Used from 03/04/2020 through 05/24/2020; (d) Level 1 lot #01211101, level 2 lot #0121102, and level 3 lot #0121103 - Used from 04/29/2020 through 07/19/2020; (e) Level 1 lot #01771101, level 2 lot #01771102, and level 3 lot #01771103 - Used from 06/24/2020 through 09/13/2020. (3) Surveyor #1 requested 2020 Levey-Jennings graphs that could be printed from the analyzer. The laboratory lead was able to print the graphs for the current lot numbers (level 1 lot 02331101, level 2 lot #02331102, and level 3 Lot #0331103), and stated on 10/28/2020 at 03:55 pm, the laboratory did not routinely print the graphs and previous lot numbers were not available for review; (4) Therefore, surveyor #1 was not able to review quality control records that included the laboratory established ranges for the 15 lot numbers listed above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory lead, the laboratory failed to perform quality control for 6 of 21 months as stated in the IQCP for Troponin I testing performed on the iSTAT 1 analyzer. Findings include: (1) On 10/26/2020 at 09:40 am, the laboratory lead stated the following to surveyor #1: (a) The laboratory performed Troponin I testing using the Siemens Status analyzer as the primary method and one iSTAT 1 analyzer (serial number 371993) was used as a back-up method; (b) An IQCP (Individualized Quality Control Plan) had been developed for the iSTAT 1 test system on 10/15/2018, and external QC (quality control) was performed monthly and with new lot numbers of cartridges. (2) Surveyor #1 reviewed QC records from January 2019 through September 2020 and identified that QC had not been tested monthly, as stated in the IQCP. QC had not been tested between: (a) 10 /10/2019 and 12/12/2019 (b) 01/14/2020 and 03/18/2020 (c) 03/18/2020 and 05/08 /2020 (d) 05/08/2020 and 09/17/2020 (3) Surveyor #1 reviewed the records with the laboratory lead and asked if there were additional records to prove that QC had been performed monthly. The laboratory lead stated on 10/26/2020 at 05:45 pm that QC had not been performed monthly 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 laboratory lead, the laboratory failed to perform a negative and positive control material 1 of 12 days of patient qualitative serum pregnancy testing. Findings include: (1) On 10/27/2020 at 09:45 am, the laboratory lead stated the following to surveyor #1: (a) The laboratory performed qualitative serum pregnancy testing using the Cardinal Health HCG Combo test kit; (b) Positive and negative serum quality control (QC) materials were performed each day of patient testing. (2) Surveyor #1 reviewed QC and patient testing records for September 2020. The review showed that negative and positive QC materials had not been performed 1 of 12 days of patient testing reviewed. The specific day was 09/16 /2020; (3) Surveyor #1 reviewed the records with laboratory lead, who stated on 10/27 /2020 at 10:15 am, negative and positive QC materials had not been performed on 09 /16/2020.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager, director of laboratory operations, laboratory support and quality management technologist, and the laboratory lead, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: STORING ALIQUOTS OF CONTROL MATERIALS (1) On 10/26/2020 at 09:45 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) The laboratory performed Troponin I testing using the Siemens Status analyzer; (b) Bio-Rad Liquichek Cardiac Markers Plus controls (level 1 and level 3) were used to perform quality control testing each day of patient testing and level 2 was used as an additional control material following calibration procedures; (c) Once thawed and opened, the control materials were aliquoted into plastic tubes and stored frozen. (2) Surveyor #1 reviewed the manufacturer's storage and stability instructions for the control material contained in the Bio-Rad control package insert. Under the heading "Aliquot-Frozen", the instructions stated, "Once thawed, opened, and stored in tightly capped aliquot vials at -20 to -70 C, this product will be stable as follows: -All analytes: 30 days"; (3) On 10/26/2020 at 10:00 am, surveyor #1 observed the contents of the Frigidaire freezer, denoted by the laboratory as freezer #1, with the following was identified (refer to D5413 for information about the freezer being a frost-free freezer and unacceptable temperatures for the control materials): (a) 6 plastic tubes containing 200 ul (microliter) aliquots of level 1 (lot #87811) - Documented on the tubes were an open date of 10/13/20 and an expiration date of 09/20/22; (b) 8 plastic tubes containing 200 ul aliquots of level 2 (lot #29882) - Documented on the tubes were an open date of 09/16/20 and an expiration date of 05 /31/21; (c) 11 plastic tubes containing 200 ul aliquots of level 3 (lot #87813) - Documented on the tubes were an open date of 10/21/20 and and expiration date of 09 /30/22. (4) Surveyor #1 determined that, based on the open dates documented on the

aliquots, the expiration dates for the materials should have been as follows: (a) Level 1 (lot #87811) - 11/12/2020 (b) Level 2 (lot #29885) - 10/16/2020 (c) Level 3 (lot #87813) - 11/20/2020 (5) Surveyor #1 reviewed the findings with the laboratory support and quality management technologist, who stated on 10/26/2021 at 10:20 am, the laboratory was not aware of the manufacturer's 30 day expiration date once the controls were aliquoted. ESTABLISHING RANGES FOR ACT CONTROLS (1) On 10/26/2020 at 09:45 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) ACT (Activated Clotting Time) was performed at the point of care in the Cath Lab using the Hemachron Signature Elite analyzer; (b) Two levels of directCheck Whole Blood control materials (normal and abnormal) were performed each 8 hours of patient testing and with a new cassette lot number. (2) On 10/27/2020, surveyor #1 reviewed the manufacturer's instructions contained in the directCHECK Whole Blood Control package insert under "Expected Values" which stated, "for the control materials, which stated, "Accriva recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests"; (3) Surveyor #1 then reviewed quality control (QC) records from January 2020 to date. The records showed for 14 of 14 lot numbers of QC materials used during the review period, the laboratory had used the package insert ranges instead of laboratory established ranges to determine acceptability of QC results as follows: (a) Normal Controls (i) Lot # #E9DNL012 - The manufacturer's range of 102-174 had been used from 01/06/2020 through 02/28/2020; (ii) Lot #J9DNL021 - The manufacturer's range of 101-188 had been used from 03/02/2020 through 05/13/2020; (iii) Lot #K9DNL022 - The manufacturer's range of 114-196 had been used from 05/13/2020 through 07/21/2020; (iv) Lot #D0DNL002 - The manufacturer's range of 118-191 had been used from 07 /22/2020 through 08/24/2020; (v) Lot #E0DNL008 - The manufacturer's range of 114-179 had been used from 08/25/2020 through 09/30/2020; (vi) Lot #EPDNL004 - The manufacturer's range of 90-209 had been used beginning 10/01/2020 and was currently in use. (b) Abnormal Controls (i) Lot #C9DLA014 - The manufacturer's range of 192-335 had been used from 01/06/2020 through 04/17/2020; (ii) Lot #H9DLA029 - The manufacturer's range of 232-350 had been used from 04/20/2020 through 05/26/2020; (iii) Lot #L9DLA032 - The manufacturer's range of 182-326 had been used from 05/27/2020 through 07/01/2020; (iv) Lot #M9DLA034 - The manufacturer's range of 194-399 had been used from 07/01/2020 though 08/24/2020; (v) Lot #D0DLA001 - The manufacturer's range of 199-356 had been used from 08/25 /2020 through 09/30/2020; (vi) Lot #G0DLA005 - The manufacturer's range of 215-344 had been used beginning 10/01/2020 and was currently in use. (4) The surveyor reviewed the findings with the laboratory lead on 10/27/2020 at 11:25 am, who stated the laboratory had used the manufacturer's provided ranges for determining acceptability of the results, as indicated above, and did not establish their own ranges. ESTABLISHING RANGES FOR TROPONIN I CONTROLS (1) On 10/26/2020 at 09:50 am, the laboratory manager and director of laboratory operations stated the following to surveyor #1: (a) Troponin I testing was performed using the Siemens Stratus analyzer as the primary method; (b) Two levels of Bio-Rad Liquichek Cardiac Markers Plus controls (level 1 and level 3) were performed each day of patient testing. (2) On 10/28/2020, surveyor #1 reviewed the manufacturer's instructions contained in the Bio-Rad Liquichek Cardiac Markers Plus Control package insert under "Assignment of Values" which stated, "The mean values and the corresponding +/- 3SD ranges printed in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from

	Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (3) Surveyor #1 then reviewed quality control (QC) records from January 2020 to date. The records showed for 4 of 4 lot numbers of QC materials used during the review period, the laboratory had used the package insert ranges instead of laboratory established ranges to determine acceptability of QC results as follows: (a) Level 1 lot #29881 and level 3 lot #29883 - The manufacturer's range of 0.16-0.45 ng/ml for level 1 and 6.28-8.61 for level 3 had been used from 01 /07/2020 through 09/16/2020; (b) Level 1 lot #87811 and level 3 lot #87813 - The manufacturer's range of 0.16-0.45 for level 1 and 4.33-6.36 for level 3 had been used beginning 10/06/2020 and was currently in use. (4) The surveyor reviewed the findings with the laboratory lead on 10/28/2020 at 11:28 am, who stated the laboratory had used the manufacturer's provided ranges for determining acceptability of the results, as indicated above, and did not establish their own ranges.
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, policies and procedures, and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions. Findings include: (1) On 10/26/2020 at 09:55 am, the laboratory manager stated to surveyor #1 units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) On 10/27 /2020, surveyor #2 reviewed the procedure titled and approved on 05/2018, "Testing Component Storage Equipment Alarms" which stated, (a) "Component storage within a controlled, optimum temperature range is essential to maintaining component safety, purity, and potency. Storage outside of defined optimum ranges may lead to red cell hemolysis, bacterial proliferation, and accelerated destruction. The Blood Bank refrigerator in the laboratory is equipped with a visual and audible alarm that is programmed to sound before components reach unacceptable storage temperatures."; (b) "C. Refrigerator, Low Alarm Activation Manual, is programmed to sound at 1.5 C."; (c) "D. Refrigerator, High Alarm Activation Manual, is programmed to sound at 5.5C."; (2) The surveyor reviewed alarm check records from 02/25/2020 through 08 /30/2020 with the following identified: (a) 02/25/2020 (i) The low alarm check result (1.6C) was documented at a temperature warmer than the programmed 1.5C; (ii) The high alarm check result (6.0C) was documented at a temperature warmer than the programmed 5.5C; (b) 05/28/2020 (i) The low alarm check result (2.0C) was documented at a temperature warmer than the programmed 1.5C; (ii) The high alarm check result (6.0C) was documented at a temperature warmer than the programmed 5.5 C; (c) 08/30/2020 (i) The low alarm check result (2.0C) was documented at a temperature warmer than the programmed 1.5C; (ii) The high alarm check result (6.0 C) was documented at a temperature warmer than the programmed 5.5C. (3) Surveyor

	#2 reviewed the records with the laboratory manager who stated on 10/27/2020 at 04: 10 pm the low alarm and high alarm had sounded at temperatures warmer than the programmed temperatures as indicated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of written policies and interview with the laboratory manager and charge nurse, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 2 of 5 units of packed red blood cells. Findings include: (1) On 10/26/2020 at 09:55 am, the laboratory manager stated to surveyor #1 the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 10/27/2020, surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Product Administration" stated: (a) "F. Monitoring Transfusions:" (i) "Routinely, vitals are taken pre-transfusion within 30 minutes before, 15 minutes after initiation of transfusion, every hour (from start time) during infusion, and one-hour from stop time transfusion. Documentation should be entered into the medical record."; (3) Surveyor #2 then reviewed records for 5 units of PRBC's (Packed Red Blood Cells) that had been transfused between 02/08/2019 through 06/02/2020 for 5 patients. The following was identified for 2 of 5 units: (a) One-hour post transfusion (i) Patient #169261 - Transfused with 1 unit of PRBC's (Packed Red Blood Cells) on 10/01/2019. One-hour from stop time transfusion vitals had not been documented. (ii) Patient #187114 - Transfused with 1 unit of PRBC's (Packed Red Blood Cells) on 03/14/2020. One-hour from stop time transfusion vitals had not been documented. (4) Surveyor #2 reviewed the findings with the charge nurse. The charge nurse stated on 10/27/2020 at 03:50 pm the one-hour post vitals had not been documented as indicated above.
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 laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 1 of 13 events. Findings include: (1) On 10/27/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. It was identified for 1 of 13 events, the attestation statements had been signed approximately 2 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Immunology Second event of 2019 - The samples had been tested on 08/15/2019 and the attestation statement had not been signed by the laboratory director until 10/16 /2019. (2) Surveyor #2 reviewed the findings with the laboratory manager and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens. The laboratory manager stated on 10/27/2020 at 02:38 pm the laboratory director failed to attest to the fact that proficiency samples were tested in the same manner as patient specimens as indicated above.
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 review of records and interview with the laboratory manager, 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 the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

	specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 6 competency evaluations performed. Findings include: (1) On 10/26/2020, surveyor #2 reviewed records for 6 persons requiring annual evaluations and performing moderate complexity testing in 2019 and 2020. The records showed the evaluations for 3 of 6 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 - The 10 /30/2019 evaluation had been performed by testing person #8 (this person had earned an Associates Degree in Science); (b) Testing Person #8 - The 09/30/2019 and 09/24 /2020 evaluations had been performed by a testing person (not a current employee) who did not meet the years of experience for a technical consultant; (c) Testing Person #6 - The 06/30/2019 and 06/24/2020 evaluations had been performed by testing person #8. (2) Surveyor #2 reviewed the records with the laboratory manager on 10/26 /2020 at 04:00 pm, and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory manager stated to surveyor #2 on 10/26 /2020 at 04:03 pm, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.