Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0668410	04/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Avoyelles Hospital Laboratory	4231 Highway 1192, Marksville, LA	

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	A Validation survey was performed at Avoyelles Hospital-CLIA # 19D0668410 on April 9 2018 through April 13, 2018. Avoyelles Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1240 CONDITION: Preanalytic systems 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical Supervisor
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 record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for one (1) of three (3) Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1, Personnel 2, and Personnel 12 serve as the Technical Consultants. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of the Technical Consultant. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant were not performed for Personnel 2. 4. In interview on April 11, 2018 at 10:06 am, Personnel 2 stated if a

	competency assessment for Technical Consultant was not seen in his personnel records then there was not one performed. Personnel 2 confirmed a competency assessment was not performed for his duties as Technical Consultant.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to the manufacturer for eight (8) of forty seven (47) patients reviewed. Refer to D5311. 2. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to the manufacturer for eight (8) of forty seven (47) patients reviewed. Findings: 1. Observation by the surveyor on April 9, 2018 revealed the laboratory was performing Lactic Acid testing on the Siemens Dimension EXL Chemistry Analyzer. 2. Review of the Siemens Dimension Lactic Acid package insert revealed under "Specimen Collection and Handling" that " Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes. Keep sample on ice and analyze promptly." 3. Review of a random selection of patient records for Lactic Acid from November 1, 2017 through April 9, 2018 revealed the laboratory did not separate Lactic Acid samples within 15 minutes and analyze promptly for the following eight (8) of forty seven (47) patients: On November 24, 2017 Patient 91 was documented as collected at 18:00 pm and received by the laboratory at 20:44 pm - two (2) hours twenty nine (29) minutes over the manufacturer's instructions of separation within 15

	minutes On January 13, 2018 Patient 92 was documented as collected at 08:45 am and received by the laboratory at 09:31 am - thirty one (31) minutes over the manufacturer's instructions of separation within 15 minutes On March 7, 2018 Patient 93 was documented as collected at 15:18 pm and received by the laboratory at 16:04 pm - thirty one (31) minutes over the manufacturer's instructions of separation within 15 minutes On November 23, 2017 Patient 94 was documented as received at 16:19 pm and resulted by the laboratory at 18:37 pm - two (2) hours eighteen (18) minutes over the manufacturer's instructions to analyze promptly On January 10, 2018 Patient 95 was documented as received at 11:13 am and resulted by the laboratory at 13:15 pm - two (2) hours two (2) minutes over the manufacturer's instructions to analyze promptly On January 12, 2018 Patient 96 was documented as received at 13:14 pm and resulted by the laboratory at 15:34 pm - two (2) hours twenty (20) minutes over the manufacturer's instructions to analyze promptly On February 6, 2018 Patient 97 was documented as received at 09:46 am and resulted by the laboratory at 11:12 am - one (1) hour twenty six (26) minutes over the manufacturer's instructions to analyze promptly On April 2, 2018 Patient 98 was documented as received at 10:30 am and resulted by the laboratory at 12:43 pm - two (2) hours thirteen (13) minutes over the manufacturer's instructions to analyze promptly 4. Interview with Personnel 2 on April 11, 2018 at 10:10 am confirmed the laboratory did not ensure Lactic Acid samples were separated within 15 minutes and analyzed promptly as required by the manufacturer.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the laboratory's " Laboratory Specimen Collection Reference Manual" given to providers revealed the following information was not included: a) Shipping/Transport requirements b) Test requirements to include time requirement for receipt of samples 2. In interview on April 11, 2018 at 10:35 am, Personnel 2 stated the identified items were not included in the laboratory's "Laboratory Specimen Collection Reference Manual."
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 observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 2. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 3. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within twenty (20) minutes according to the manufacturer for ten (10) of twenty eight (28) patients reviewed. Refer to D5411 II. 4. The laboratory failed to document acceptable patient donors for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 III. 5. The laboratory failed to ensure the Sickle Sol kit test in use had not exceeded its expiration date. Refer to D5417 I. 6. The laboratory failed to ensure Blood Bank Quality Control reagents had not exceeded their expiration date. Refer to D5417 II. 7. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for the Siemens Dade Sickle Sol Test. Refer to D5423. 8. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445. 9. The laboratory failed to perform three (3) levels of controls prior to patient testing for Complete Blood Counts (CBC) per laboratory policy. Refer to D5447 I. 10. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for eleven (11) of twelve (12) analytes. Refer to D5447 II. 11. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for Alkaline Phosphatase for one (1) of thirty one (31) days reviewed. Refer to D5447 III. 12. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469. 13. The laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for one (1) of three hundred seventy three (373) days reviewed. Refer to D5551. 14. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
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 record review and interview with personnel, the laboratory failed to have a

	complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the manual did not include detailed instructions for the following: a) Quality Control Range Establishment: instructions on how to establish the laboratory's means and ranges for Bio-Rad QC, Sysmex XT-2000i QC, and Sysmex Ca-500 QC. b) Individualized Quality Control Plan (IQCP): who is going to perform, what is going to be performed, when it is going to be performed, where it is going to be performed and how it will be performed. What data is needed to support the IQCP and how that data will be retained. Also what will be the acceptability criteria, and who needs to review and sign off on the IQCP and when to implement the outcome. c) Performance specifications for Laboratory Instrumentation to include: *Policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. * Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges. * Policies and procedures for when data from the studies for precision, accuracy, reportable and reference ranges fail to meet acceptability criteria. d) Proficiency Testing: Instructions to include the rotation of personnel performing testing e) Blood Bank: Instructions for laboratory on how to investigate Transfusion Reactions. 2. Interview with Personnel 2 on April 11, 2018 confirmed the laboratory did not have a complete policy and procedure manual.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory on April 10, 2018 revealed the laboratory receives BD BACTEC culture bottles. 2. Further observation revealed the laboratory utilized the following BD BACTEC culture bottles: BD BACTEC Peds Plus/F Culture Vials Lot # 7311953 BD BACTEC Plus Aerobic/F Culture Vials Lot # 734086 BD BACTEC Lytic/10 Anaerobic Culture Vials Lot # 70283792 3. Review of the the BD BACTEC culture bottles' package inserts revealed "Prior to use, each vial should be examined for evidence of damage, contamination or deterioration. Vials displaying evidence of damage or contamination such as leakage, cloudiness, discoloration (darkening), bulging or depressed septum should not be used." 4. In interview on April 12, 2018 at 4:20 pm, Personnel 14 stated the laboratory the blood culture bottles are inspected prior to use. Personnel 14 further stated the laboratory does not document visual inspection of the culture bottles. II. Based on observation, record review, and interview with personnel, the laboratory failed to ensure that patient samples for Ammonia testing are analyzed within twenty (20) minutes according to the manufacturer for ten (10) of twenty eight (28) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on April 9, 2018 revealed the laboratory utilizes the Siemens Dimension EXL analyzer for Ammonia testing. 2. Review of the Siemens Dimension package insert for Ammonia under "Specimen Collection and Handling" revealed "The tube should be completely filled, stored

tightly capped on ice, centrifuged immediately and analyzed within 20 minutes." 3. Review of patient records for Ammonia from November 10, 2017 through April 9, 2018 revealed the laboratory failed to analyze the following ten (10)Ammonia samples within twenty (20) minutes. On November 28, 2017, the sample for Patient 265 was documented as collected at 5:59 am, received in laboratory at 7:33 am; exceeded manufacturer requirements by one (1) hour and fourteen (14) minutes. On December 4, 2017, the sample for Patient 266 was documented as collected at 4:35 am, received in laboratory at 8:04 am ; exceeded manufacturer requirements by three (3) hours and nine (9) minutes. On December 5, 2017,the sample for Patient 267 was documented as collected at 13:08, received in laboratory at 15:28 ; exceeded manufacturer requirements by two (2) hours. On December 11, 2017, the sample for Patient 268 was documented as collected at 4:45 am, received in laboratory at 6:33 am ; exceeded manufacturer requirements by one (1) hour and twenty eight (28) minutes. On December 12, 2017, the sample for Patient 269 was documented as collected at 15: 15, received in laboratory at 16:15; exceeded manufacturer requirements by forty (40) minutes. On December 13, 2017, the sample for Patient 270 was documented as collected at 10:15, received in laboratory at 10:42 am; exceeded manufacturer requirements by seven (7) minutes. On January 2, 2018, the sample for Patient 271 was documented as collected at 5:25 am, received in laboratory at 7:31 am; exceeded manufacturer requirements by forty six (46) minutes. On February 8, 2018, the sample for Patient 272 was documented as collected at 6:10 am, received in laboratory at 7:45 am; exceeded manufacturer requirements by one (1) hour and fifteen (15) minutes. On February 27, 2018, the sample for Patient 273 was documented as collected at 13:00, received in laboratory at 16:49; exceeded manufacturer requirements by two (2) hours and twenty nine (29) minutes. On April 2, 2018, the sample for Patient 274 was documented as collected at 6:10 am, received in laboratory at 6:53 am; exceeded manufacturer requirements by thirty three (33) minutes. 4. In interview on April 11, 2018 at 10:52 am, Personnel 2 stated the identified ammonia samples should have been rejected. Personnel 2 further stated the samples came from outside facilities: nursing homes, home health and hospice. 39352 III. Based on observation, record review, and interview with personnel, the laboratory failed to document acceptable patient donors for Prothrombin Time (PT) normal patient mean studies. Findings: 1. Observation by surveyors during laboratory tour on April 9, 2018 revealed the laboratory utilized the Sysmex Ca 500 analyzer for PT and International Normalized Ratio (INR) testing. 2. Review of the laboratory's "Establishment of Normal PT curve and Normal PT with each new lot of PT reagent" revealed under "Establishing a new normal patient mean" the laboratory collects specimens from 20 normal patients and performs a PT using the new lot of thromboplastin reagent. Please note that certain substances such as: alcohol, antibiotics, aspirin, oral contraceptives, and Vitamin K are known to interfere with Prothrombin Time results. Do not select patients taking any of these substances for your pool to establish the new normal patient mean. Patients collected for specimens to be used for establishing the normal PT must be screened by questioning whether they have used or taken any of these substances within 24 hours. 3. Review of the most recent change in Innovin reagent (Lot # 539393, Exp 08-10-19) revealed the laboratory calculated a mean of 10.1 seconds utilizing twenty nine (29) donors. However, the laboratory did not ensure these individuals met the above criteria required by the manufacturer of normal donors. 4. In interview on April 12, 2018 at 11:30 am. Personnel 5 stated the laboratory did not have a normal patient questionnaire established at the time the study was performed. 5. In further interview on April 12, 2018 at 12:01 pm, Personnel 5 confirmed that acceptable donors were not documented for use in the normal mean patient study. 6. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs two thousand three hundred (2300) PT/INR tests annually.

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: I. Based on observation, record review and interview with personnel, the laboratory failed to ensure the Sickle Sol kit test in use had not exceeded its expiration date. Findings: 1. Observation by surveyor during laboratory tour on April 9, 2018 revealed the laboratoy utilizes the Siemens Dade Sickle Sol test. 2. Review of the Dade Sickle Sol Quality Control (QC) log revealed the Sickle Sol test kit lot number did not get documented; However, the expiration date was documented as 01/04/2018. A new lot was not documented until 02/20/2018. 3. Further review of QC records revealed the laboratory performed the following patients with an expired test kit: Patients 101 - 102 performed on January 30, 2018 Patient 103 performed on January 31, 2018 Patients 104 - 106 performed on February 6, 2018 Patients 107 - 108 performed on February 7, 2018 4. In interview on April 12, 2018 at 10:50 am, Personnel 3 stated that the records showed an expired kit was in use and there was no documentation of a lot number. Personnel 2 confirmed the above patients were tested on an expired kit. II. Based on record review and interview with personnel, the laboratory failed to ensure Blood Bank Quality Control reagents had not exceeded their expiration date. Findings: 1. Review of the "Blood Bank Daily Quality Control Record Reagent and Control Lot #'s" for July 2017 revealed the laboratory documented Lot # CNF 067 with an expiration date of 07/04/17; However, the laboratory did not document a new lot until August 1, 2017. 2. Review of the laboratory's Blood Bank Quality Control (QC) and patient records revealed the following eleven (11) of twenty six (26) patients reviewed were performed on expired reagents: *Patients 65 performed on July 7, 2017 *Patient 66 performed on July 9, 2017 *Patient 67 performed on July 12, 2017 *Patient 68 performed on July 13, 2017 *Patients 69 - 70 performed on July 14, 2017 *Patients 71 - 73 performed on July 20, 2017 * Patient 74 performed on July 22, 2017 *Patient 75 performed on July 31, 2017 3. In interview on April 10, 2018 at 01: 58 pm, Personnel 2 stated he was unaware that this had happened. Personnel 2 confirmed the above patients were tested with expired reagents.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for the Siemens Dade Sickle Sol Test. Findings: 1. Observation by surveyor during the laboratory tour on April 9, 2018 revealed the laboratory utilized the Siemens Dade Sickle Sol Test. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed, written instructions for performance specification studies. 3. Review of laboratory records revealed the laboratory did not perfrom any performance specification studies for the Siemens Dade Sickle Sol test. 4. In interview on April 12, 2018, Personnel 2 stated he thought the Sickle Sol test was a waived test and did not need performance studies performed. Personnel 2 confirmed that performance studies were not performed.
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 observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyors during the laboratory tour on April 9, 2018 revealed the laboratory utilizes the Triage Meter Pro analyzer for D-Dimer testing. 2. Review of the laboratory's "Triage D-dimer IQCP" revealed the following component was not included: a) Quality Assessment Plan 3. In interview on April 11, 2018 at 3:28 pm, Personnel 2 stated the laboratory's IQCP did not include a Quality Assessment plan. Personnel 2 further stated the laboratory is currently working on a plan. 4. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 150 D-dimer tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to perform three (3) levels of controls prior to patient testing for Complete Blood Counts (CBC) per laboratory policy. 1. Observation by the surveyors during laboratory tour on April 9, 2018 revealed the laboratory utilizes the Sysmex XT-200i

for Complete Blood Counts (CBC) testing. 2. Review of the laboratory's "Quality Control Policy" under the "Hematology" section revealed "The SysmexControls (three levels) are run at a minimum of once per 8 hours. Times: 700, 1500, 2300." 3. In interview on April 12, 2018 at 9:31 am, Personnel 3 stated the laboratory performs quality controls for CBC testing at 7:00 am, 3:00 pm, and 11:00 pm, +/- 30 minutes. 4. Review of the quality control (QC) records for March 2018 revealed the laboratory did not perform three (3) levels of QC prior to patient testing on the following date and time: March 7, 2018: 7:00 am QC 5. Review of patient test records for March 7, 2018 revealed the following patients were reported without performance of QC prior: Patient 258 Patient 259 Patient 260 Patient 261 Patient 262 Patient 263 Patient 264 6. In interview on April 12, 2018 at 10:21 am, Personnel 3 stated she was unaware the morning QC was missed on the identified date. Personnel 3 confirmed the morning QC was not performed on March 7, 2018. 39352 II. Based on observation, record review, and interview with personnel, the laboratory failed to perform two (2) levels of Quality Control prior to patient testing for eleven (11) of twelve (12) analytes. Findings: 1. Observation by surveyors during laboratory tour on April 9, 2018 revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer for the following tests: *Carbamazepine, Ferritin, Thyroxine (T4), Vitamin B12, Lactic Acid, Gentamycin, PreAlbumin, Phenobarbital, Salicylates, Triiodothyronine (T3) Uptake, and Ammonia. 2. Review of the laboratory's Quality Control (QC) policy revealed testing personnel are to perform two (2) levels of quality control every twenty four (24) hours prior to patient testing. 3. Review of QC and patient test records from September 11, 2017 through April 11, 2018 revealed the laboratory did not perform two (2) levels of QC prior to patient testing for the following: a) Carbamazepine - five (5) of twenty three (23) patients reviewed *Patient 235 resulted November 16, 2017 at 09:45 am (QC done November 15, 2017 at 09:32 am then not again until November 16, 2017 at 12:34 pm) *Patient 5 resulted November 20, 2017 at 06:31 am (QC done November 17, 2017 at 09:09 am then not again until November 20, 2017 at 10:13 am) *Patient 4 resulted December 26, 2017 at 07:52 am (QC done December 22, 2017 at 12:12 pm then not again until December 26, 2017 at 08:51 am) *Patient 2 resulted February 21, 2018 at 07:07 am (QC done February 19, 2018 at 10:09 am then not again until February 21, 2018 at 08:07 am) *Patient 236 resulted March 21, 2018 at 06:17 am (QC done March 19, 2018 at 07:33 am then not again until March 21, 2018 at 07:14 am) b) Ferritin - seven (7) of eighty four (84) patients reviewed *Patient 10 resulted November 18, 2017 at 09:41 am (QC done November 17, 2017 at 09:08 am then not again until November 18, 2017 at 12:28 pm) *Patient 214 resulted December 28, 2017 at 16:57 pm (QC done December 27, 2017 at 15:29 pm then not again until December 29, 2017 at 08:46 am) *Patient 215 resulted January 23, 2018 at 14:41 pm (QC done January 22, 2018 at 09:46 am then not again until January 24, 2018 at 09:04 am) *Patient 216 resulted January 27, 2018 at 10:00 am (QC done January 24, 2018 at 09:04 am then not again until January 29, 2018 at 09:07 am) *Patient 217 resulted January 26, 2018 at 12:19 pm (QC done January 24, 2018 at 09:04 am then not again until January 29, 2018 at 09:07 am) *Patient 218 resulted February 15, 2018 at 13:13 pm (QC done February 14, 2018 at 10:41 am then not again until February 16, 2018 at 10:36 am) *Patient 6 resulted March 27, 2018 at 16:21 pm (QC done March 26, 2018 at 11:27 am then not again until March 28, 2018 at 09:54 am) c) Thyroxine (T4) - one (1) of forty four (44) patients reviewed *Patient 27 resulted February 28, 2018 at 08: 11 am (QC done February 26, 2018 at 10:09 am then not again until February 28, 2018 at 09:58 am) d) Vitamin B12 - thirteen (13) of one hundred one (101) patients reviewed *Patient 20 resulted November 20, 2017 at 06:35 am (QC done November 17, 2017 at 09:08 am then not again until November 20, 2017 at 12:31 pm) *Patient 219 resulted November 28, 2017 at 12:13 pm (QC done November 27, 2017 at 09:01 am then not again until November 29, 2017 at 13:34 pm) *Patient 220 resulted

December 14, 2017 at 12:13 pm (QC done December 13, 2017 at 10:15 am then not again until December 15, 2017 at 10:15 am) *Patient 19 resulted December 26, 2017 at 13:21 pm (QC done December 22, 2017 at 10:11 am then not again until December 26, 2017 at 14:22 pm) *Patient 221 resulted January 2, 2018 at 07:06 am (QC done December 29, 2017 at 08:46 am then not again until January 3, 2018 at 07:42 am) *Patient 222 resulted January 23, 2018 at 14:41 pm (QC done January 22, 2018 at 09: 46 am then not again until January 24, 2018 at 09:04 am) *Patient 223 resulted January 25, 2018 at 16:26 pm (QC done January 24, 2018 at 09:04 then not again until January 29, 2018 at 09:07 am) *Patient 225 resulted April 2, 2018 at 07:08 am (QC done March 30, 2018 at 09:35 am then not again until April 4, 2018 at 09:04 am) *Patient 226 resulted April 2, 2018 at 07:29 am (QC done March 30, 2018 at 09:35 am then not again until April 4, 2018 at 09:04 am) *Patient 227 resulted April 2, 2018 at 07:37 am (QC done March 30, 2018 at 09:35 am then not again until April 4, 2018 at 09:04 am) *Patient 228 resulted April 2, 2018 at 09:28 am (QC done March 30, 2018 at 09:35 am then not again until April 4, 2018 at 09:04 am) *Patient 229 resulted April 2, 2018 at 12:31 pm (QC done March 30, 2018 at 09:35 am then not again until April 4, 2018 at 09:04 am) e) Lactic Acid - one (1) of forty seven (47) patients reviewed *Patient 230 resulted November 23, 2017 at 15:51 pm (QC done November 22, 2017 at 07:18 am then not again until November 24, 2017 at 12:29 pm) f) Gentamycin - three (3) of ten (10) patients reviewed *Patient 235 resulted December 31, 2017 at 11:48 am (QC done December 29, 2017 at 08:11 am then not again until December 31, 2017 at 16:39 pm) *Patient 32 resulted January 16, 2018 at 17:05 pm (QC done January 15, 2018 at 12:33 pm then not again until January 17, 2018 at 09:12 am) *Patient 31 resulted March 22, 2018 at 13:09 pm (QC done March 21, 2018 at 07: 14 am then not again until March 22, 2018 at 14:10 pm) g) PreAlbumin - five (5) of eighty eight (88) patient reviewed *Patient 14 resulted December 26, 2017 at 07:53 am (QC done December 22, 2017 at 12:12 pm then not again until December 26, 2017 at 08:51 am) *Patient 13 resulted January 8, 2018 at 06:59 am (QC done January 5, 2018 at 12:29 pm then not again until January 8, 2018 at 08:31 am) *Patient 234 resulted January 8, 2018 at 07:07 am (QC done January 5, 2018 at 12:29 pm then not again until January 8, 2018 at 08:31 am) *Patient 231 resulted February 27, 2018 at 18:17 pm (QC done February 26, 2018 at 09:27 am then not again until February 28, 2018 at 08:22 am) *Patient 11 resulted March 21, 2018 at 06:07 am (QC done March 19, 2018 at 08:02 am then not again until March 21, 2018 at 07:14 am) h) Phenobarbital - six (6) of thirty two (32) patients reviewed *Patient 63 resulted November 15, 2018 at 06:48 am (QC done November 13, 2018 at 08:19 am then not again until November 15, 2018 at 09:32 am) *Patient 232 resulted December 4, 2017 at 07:25 am (QC done December 1, 2017 at 11:39 am then not again until December 4, 2017 at 09:12 am) *Patient 233 resulted December 4, 2017 at 07:28 am (QC done December 1, 2017 at 11:39 am then not again until December 4, 2017 at 09:12 am) *Patient 62 resulted December 28, 2017 at 15:29 pm (QC done December 27, 2017 at 15:00 pm then not again until December 29. 2017 at 08:11 am) *Patient 61 resulted January 17, 2018 at 07:22 am (QC done January 15, 2018 at 12:33 pm then not again until January 17, 2018 at 09:12 am) *Patient 60 resulted February 21, 2018 at 07:07 am (QC done February 19, 2018 at 07:11 am then not again until February 21, 2018 at 08:07 am) i) Salicylates - seven (7) of fifty one (51) patients reviewed *Patient 237 resulted December 8, 2017 at 00:58 am (QC done December 6, 2017 at 11:37 am then not again until December 8, 2017 at 01:11 am) *Patient 238 resulted December 14, 2017 at 16:54 pm (QC done December 13, 2017 at 10:15 am then not again until December 15, 2017 at 10:15 am) *Patient 239 resulted December 19, 2017 at 20:03 pm (QC done December 18, 2017 at 10:14 am then not again until December 20, 2017 at 10:45 am) *Patient 53 resulted December 24, 2017 at 19:24 pm (QC done December 22, 2017 at 09:50 am then not again until December 24, 2017 at 19:56 pm)

*Patient 240 resulted December 31, 2017 at 23:59 pm (QC done December 30, 2017 at 07:39 am then not again until January 1, 2018 at 00:34 am) *Patient 241 resulted January 26, 2018 at 16:06 pm (QC done January 24, 2018 at 09:04 am then not again until January 27, 2018 at 22:24 pm) *Patient 242 resulted January 26, 2018 at 21:31 pm (QC done January 24, 2018 at 09:04 am then not again until January 27, 2018 at 22:24 pm) j) T3 Uptake - seven (7) of twenty four (24) patient reviewed *Patient 49 resulted November 17, 2017 at 07:34 am (QC done November 15, 2017 at 09:32 am then not again until November 17, 2017 at 09:09 am) *Patient 243 resulted December 4, 2017 at 10:04 am (QC done December 1, 2017 at 11:39 am then not again until December 4, 2017 at 12:29 pm) *Patient 244 resulted December 18, 2017 at 07:18 am (QC done December 15, 2017 at 12:26 pm then not again until December 18, 2017 at 08:41 am) *Patient 245 resulted December 20, 2017 at 07:51 am (QC done December 18, 2017 at 08:41 am then not again until December 20, 2017 at 08:43 am) *Patient 246 resulted March 7, 2018 at 07:45 am (QC done March 5, 2018 at 10:19 am then not again until March 7, 2018 at 09:53 am) *Patient 247 resulted March 28, 2018 at 09:37 am (QC done March 26, 2018 at 07:49 am then not again until March 28, 2018 at 10:23 am) *Patient 248 resulted April 4, 2018 at 15:08 pm (QC done April 2, 2018 at 08:55 am then not again until April 4, 2018 at 16:03 pm) k) Ammonia - twelve (12) of twenty eight (28) patient reviewed *Patient 44 resulted November 10, 2017 at 07: 32 am (QC done November 8, 2017 at 11:21 am then not again until November 10, 2017 at 08:21 am) *Patient 249 resulted November 11, 2017 at 08:48 am (QC done November 10, 2017 at 08:21 am then not again until November 11, 2017 at 10:35 am) *Patient 250 resulted December 2, 2017 at 19:40 pm (QC done December 1, 2017 at 11:24 am then not again until December 2, 2017 at 20:04 pm) *Patient 43 resulted December 4, 2017 at 08:04 am (QC done December 2, 2017 at 20:04 pm then not again until December 4, 2017 at 08:49 am) *Patient 251 resulted December 5, 2017 at 15:28 pm (QC done December 4, 2017 at 12:01 pm then not again until December 6, 2017 at 11:06 am) *Patient 252 resulted December 12, 2017 at 16:15 pm (QC done December 11, 2017 at 12:00 pm then not again until December 13, 2017 at 10:30 am) *Patient 253 resulted December 25, 2017 at 12:27 pm (QC done December 23, 2017 at 10:54 am then not again until December 28, 2017 at 07:09 am) *Patient 254 resulted December 27, 2017 at 22:27 pm (QC done December 23, 2017 at 10:54 am then not again until December 28, 2017 at 07:09 am) *Patient 42 resulted January 2, 2018 at 07:32 am (QC done December 29, 2017 at 06:48 am then not again until January 2, 2018 at 08:17 am) *Patient 255 resulted January 9, 2018 at 12:50 pm (QC done January 5, 2018 at 12:50 pm then not again until January 10, 2018 at 14:48 pm) *Patient 256 resulted February 12, 2018 at 06:31 am (QC done February 9, 2018 at 09: 26 am then not again until February 12, 2018 at 07:13 am) *Patient 257 resulted March 12, 2018 at 08:04 am (QC done March 9, 2018 at 12:52 pm then not again until March 12, 2018 at 09:38 am) 4. In interview on April 11, 2018 at 03:36 pm, Personnel 2 stated he was unaware that QC was not performed prior to patient testing. Personnel 2 confirmed the above patients were resulted without two levels of QC being performed. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following tests annually: a) Carbamazepine - forty (40) b) Ferritin - two hundred forty (240) c) T4 Total - ninety (90) d) Digoxin - one hundred sixty (160) e) B12 - four hundred (400) f) Lactic Acid - ninety (90) g) Gentamycin - forty (40) h) Pre Albumin - two hundred fifty (250) i) Phenobarbital - one hundred (100) j) Salicylates - one hundred forty four (144) k) T3 Uptake - one hundred (100) l) Ammonia - seventy five (75) III. Based on observation, record review, and interview with personnel, the laboratory failed to perform two (2) levels of Quality Control prior to patient testing for Alkaline Phosphatase for one (1) of thirty one (31) days reviewed. Findings: 1. Observation by surveyors during laboratory tour on April 9, 2018 revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer

	for Alkaline Phosphatase (ALP). 2. Review of the laboratory's Quality Control (QC) policy revealed testing personnel are to perform two (2) levels of quality control every twenty four (24) hours prior to patient testing. 3. Review of QC and patient test records from May 2017 revealed the laboratory did not perform two (2) levels of QC for the following: Patients 115 - 140: resulted on May 25, 2017 4. In interview on April 12, 2018 at 10:00 am, Personnel 2 confirmed that the above patients were resulted without two (2) levels of QC being performed. 5. Review of the Task 1 & 3 form revealed the laboratory performs nine thousand one hundred (9100) ALP tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Findings: 1. Observation by surveyors during laboratory tour on April 9, 2018, revealed the laboratory utilizes the Siemens Dimension EXL with LM analyzer with the following BioRad Controls for chemistry testing: a. Bio Rad Liquid Unassayed Multiqual b. Bio Rad Liquichek Ethanol/Ammonia c. Bio Rad Liquichek Cardiac Markers Plus d. Bio Rad Lyphochek Diabetes e. Bio Rad Liquichek Immunoassay Plus f. Bio Rad Liquichek Immunology 2. Review of the manufacturer's package insert for the BioRad controls under the "Assignment of Values" section revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 3. Review of the laboratory's policy and procedure manual revealed no policy was written for how the laboratory should establish its own acceptable ranges. 4. Review of QC records revealed the laboratory utilized the following BioRad Controls without establishing their own means or ranges: a. Bio Rad Liquid Unassayed Multiqual Lot 47951 Exp 01 /31/20 Lot 47953 Exp 01/31/20 b. Bio Rad Liquichek Ethanol/Ammonia Lot 54171 Exp 05/31/18 Lot 54173 Exp 05/31/18 c. Bio Rad Liquichek Cardiac Markers Plus Lot 29871 Exp 04/30/20 Lot 29873 Exp 04/30/20 d. Bio Rad Lyphochek Diabetes Lot 33951 Exp 06/30/19 Lot 33952 Exp 06/30/19 e. Bio Rad Liquichek Immunoassay Plus Lot 40941 Exp 06/30/19 Lot 40943 Exp 06/30/19 f. Bio Rad Liquichek Immunology Lot 66351 Exp 04/30/18 Lot 66353 Exp 04/30/18 5. In interview on April 12, 2018 at 02:10 pm, Personnel 2 stated the laboratory uses the peer data initially then monitors and adjusts ranges as needed but does not keep any documentation of range adjustment. Personnel 2 confirmed the laboratory does not establish their own means and ranges.

D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for one (1) of three hundred seventy three (373) days reviewed. Findings: 1. Review of laboratory's procedure manual revealed that Reagent controls are to be performed daily. 2. In interview on March 10, 2018 at 01:20 pm, Personnel 2 stated that Blood Bank QC is performed every morning at 07:00 am whether there is a patient or not. 3. Review of the Blood Bank QC and patient records from April 1, 2017 through April 9, 2018 revealed the laboratory did not perform and document daily QC prior to patient testing for the following dates: April 29, 2017 - no ABO/Rh QC documented (QC documentd on April 28, 2018 and then not again until April 30, 2018. *Patient 64 - testing performed /resulted April 29, 2018 at 09:15 am 4. In interview on April 10, 2018 at 01:58 pm, Personnel 2 stated he was unaware that QC had not been performed. Personnel 2 confirmed that QC was not documented for the above date and that patient testing was performed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's policy and procedure manual revealed a "Quality Assurance Monitor" policy which included the following analytic monitors: a) "Monitor # A1: Reagent Storage and Testing Environment" b) "Monitor # A2: Failures of QC, Calibration, Proficiency" c) " Monitor # A3: QC Documentation" d) "Monitor # A4: QC Frequency" e) "Monitor # A5: Coagulation INR" f) "Monitor # A6: Maintenance of Equipment" 2. Review of the laboratory's policy and procedure manual, quality control records, and patient test records revealed the laboratory's monitors did not identify the following issues: a. The laboratory failed to have a complete policy and

	procedure manual. Refer to D5403. b. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. c. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within twenty (20) minutes according to the manufacturer for ten (10) of twenty eight (28) patients reviewed. Refer to D5411 II. d. The laboratory failed to document acceptable patient donors for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 III. e. The laboratory failed to ensure the Sickle Sol kit test in use had not exceeded its expiration date. Refer to D5417 I. f.. The laboratory failed to ensure Blood Bank Quality Control reagents had not exceeded their expiration date. Refer to D5417 II. g. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges, analytical sensitivity, and specificity for the Siemens Dade Sickle Sol Test. Refer to D5423. h. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445. i. The laboratory failed to perform three (3) levels of controls prior to patient testing for Complete Blood Counts (CBC) per laboratory policy. Refer to D5447 I. j. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for eleven (11) of twelve (12) analytes. Refer to D5447 II. k. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for Alkaline Phosphatase for one (1) of thirty one (31) days reviewed. Refer to D5447 III. l. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469. m. The laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for one (1) of three hundred seventy three (373) days reviewed. Refer to D5551. 3. Interview with Personnel 2 confirmed the laboratory's monitors did not identify and correct the above deficiencies found.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 2. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 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 D6031.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to the manufacturer for eight (8) of forty seven (47) patients reviewed. Refer to D5311. 2. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 4. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within twenty (20) minutes according to the manufacturer for ten (10) of twenty eight (28) patients reviewed. Refer to D5411 II. 5. The laboratory failed to document acceptable patient donors for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 III.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445. 2. The laboratory failed to perform three (3) levels of controls prior to patient testing for Complete Blood Counts (CBC) per laboratory policy. Refer to D5447 I. 3. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for eleven (11) of twelve (12) analytes. Refer to D5447 II. 4. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for Alkaline Phosphatase for one (1) of thirty one (31) days reviewed. Refer to D5447 III. 5. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for one (1) of three (3) Technical Consultants were complete. Refer to D5209. 2. The Technical Consultants failed to assess personnel competency for one (1) of eleven (11) testing personnel reviewed. Refer to D6046. 3. The Technical Consultants failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6051.
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 record review, and interview with laboratory personnel, 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 D5403.
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 record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 3. The Technical Consultants failed to assess personnel competency for one (1) of eleven (11) testing personnel reviewed. Refer to D6046. 4. The Technical Consultants failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6051.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure that patient samples for Lactic Acid testing are separated within fifteen (15) minutes after collection and analyzed promptly according to the manufacturer for eight (8) of forty seven (47) patients reviewed. Refer to D5311. 2. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 4. The laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411 I. 5. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within twenty (20) minutes according to the manufacturer for ten (10) of twenty eight (28) patients reviewed. Refer to D5411 II. 6. The laboratory failed to document acceptable patient donors for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 III.
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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445. 2. The laboratory failed to perform three (3) levels of controls prior to patient testing for Complete Blood Counts (CBC) per laboratory policy. Refer to D5447 I. 3. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for eleven (11) of twelve (12) analytes. Refer to D5447 II. 4. The laboratory failed to perform two (2) levels of Quality Control prior to patient testing for Alkaline Phosphatase for one (1) of thirty one (31) days reviewed. Refer to D5447 III. 5. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for chemistry testing. Refer to D5469.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to assess personnel competency for one (1) of eleven (11) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1, Personnel 2, and Personnel 12 served as Technical Consultants. 2. Further review of the laboratory's CMS-209 form revealed Personnel 2 also served as testing personnel. 3. Review of Personnel 2's competency assessment for 2017 for his duties as testing personnel revealed Personnel 1 nor Personnel 12 completed the assessment. 4. In interview on April 10, 2018 at 3:50 pm, Personnel 2 stated he performed the 2017 competency assessments for all testing personnel. Personnel 2 confirmed he signed his own 2017 assessment as "Laboratory Director (designee)."
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 2 Personnel 3 Personnel 4 Personnel 5

	Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 13 2. Review of the laboratory's "Proficiency Testing" policy revealed the following; a) "External Proficiency Tests: These samples are tested in the same manner as the Clinical Laboratory tests patient specimens, that is with the Clinical Laboratory's regular patient workload by personnel who routinely perform the testing in the Clinical Laboratory, using the Clinical Laboratory's routine methods." b) "Internal Proficiency Tests: At least two times per year, blind specimens shall be introduced into the routine workload of all Clinical Laboratory departments." 3. Review of the laboratory's 2017 College of American Pathologists (CAP) Proficiency Test (PT) records revealed the laboratory rotates personnel performing PT testing; however, not all personnel are assessed. 4. Review of 2017 competency assessments for the testing personnel revealed the laboratory did not have documentation of performance of internal blind sample testing. 5. In interview on April 10, 2018 at 11:30 am, Personnel 2 stated for PT the laboratory rotates staff through events in a two (2) year period. Personnel 2 further stated no more than one (1) person participates in each event. 6. In interview on April 11, 2018 at 8:56 am, Personnel 2 stated the laboratory is not performing blind sample testing annually. Personnel 2 confirmed all testing personnel are not assessed annually for all analytes through blind sample or proficiency testing.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory director failed to ensure the laboratory established and verified performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Siemens Dade Sickle Sol test. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure that quality control programs are maintained in Immunohematology. Refer to D6093. 4. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6103.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 observation, record review and interview with laboratory personnel, the laboratory director failed to ensure the laboratory established and verified performance specifications for accuracy, precision reportable and reference ranges

	(normal values) and analytical sensitivity and specificity for the Siemens Dade Sickle Sol test. Refer to D5423.
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 observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417 I.
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 record review and interview with personnel, the Laboratory Director failed to ensure that quality control programs are maintained in Immunohematology. Findings: 1. The laboratory failed to ensure Blood Bank Quality Control reagents had not exceeded their expiration date. Refer to D5417 II. 2. The laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for one (1) of three hundred seventy three (373) days reviewed. Refer to D5551.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The Technical Supervisor failed to evaluate the competency for one (1) of eleven (11) testing personnel reviewed. Refer to D6120. 2. The Technical Supervisor failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6125.

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 record review and interview with personnel, the Technical Consultant failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor failed to ensure laboratory personnel performed test methods as required. Refer to D6112. 2. The Technical Supervisor failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Siemens Dade Sickle Sol Test. Refer to D6115. 3. The Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6117. 4. The Technical Supervisor failed to evaluate the competency for one (1) of eleven (11) testing personnel reviewed. Refer to D6120. 5. The Technical Supervisor failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6125.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Technical Supervisor failed to ensure laboratory personnel performed test methods as required. Refer to D5417 I.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and 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 record review and interview with personnel, the Technical Supervisor failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Siemens Dade Sickle Sol Test. Refer to D5423.
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 record review and interview with personnel, the Technical Supervisor(s) failed to ensure that quality control programs are established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to ensure Blood Bank Quality Control reagents had not exceeded their expiration date. Refer to D5417 II. 2. The laboratory failed to document the Quality Control (QC) for ABO, Rh, Antibody Screen (AbScr), and Compatibility (Xmatch) testing prior to patient testing for one (1) of three hundred seventy three (373) days reviewed. Refer to D5551.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to evaluate the competency for one (1) of eleven (11) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1 served as Technical Supervisor and Personnel 2 as General Supervisor. 2. Further review of the laboratory's CMS-209 form revealed Personnel 2 served as testing personnel. 3. Review of Personnel 2's competency assessment for 2017 for his duties as testing personnel revealed Personnel 1 did not complete the assessment. 4. In interview on April 10, 2018 at 3:50 pm, Personnel 2 stated he performed the 2017 competency assessments for all testing personnel. Personnel 2 confirmed he signed his own 2017 assessment as "Laboratory Director (designee)."
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 2 Personnel 3 Personnel 4 Personnel 5

	Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 13 2. Review of the laboratory's "Proficiency Testing" policy revealed the following; a) "External Proficiency Tests: These samples are tested in the same manner as the Clinical Laboratory tests patient specimens, that is with the Clinical Laboratory's regular patient workload by personnel who routinely perform the testing in the Clinical Laboratory, using the Clinical Laboratory's routine methods." b) "Internal Proficiency Tests: At least two times per year, blind specimens shall be introduced into the routine workload of all Clinical Laboratory departments." 3. Review of the laboratory's 2017 College of American Pathologists (CAP) Proficiency Test (PT) records revealed the laboratory rotates personnel performing PT; however, not all analytes are performed by each personnel. 4. Review of competency assessments for the testing personnel revealed the laboratory did not have documentation of performance of internal blind sample testing. 5. In interview on April 10, 2018 at 11: 30 am, Personnel 2 stated for PT the laboratory rotates staff through events in a two (2) year period. Personnel 2 further stated no more than one (1) person participates in each event. 6. In interview on April 11, 2018 at 8:56 am, Personnel 2 stated the laboratory is not performing blind sample testing annually. Personnel 2 confirmed all testing personnel are not assessed annually for all analytes through blind sample or proficiency testing.