Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463303	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Caddo Medical Center	715 S Pine, Vivian, 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 CERTIFICATION SURVEY was performed at North Caddo Medical Center - CLIA # 19D0463303 on May 21, 2018 through May 25, 2018. North Caddo Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1409 CONDITION: Technical Consultant performing moderate complexity testing
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 address competency for the Technical Consultant and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following: *Personnel 2 and Personnel 3 serves as the laboratory's Technical Consultants *Personnel 4 serves as the laboratory's General Supervisor 2. Review of the laboratory's policies and procedures revealed the laboratory did have a policy for competency assessment for the Technical Consultant and General Supervisor; However, the policy did not include the frequency in which the competency assessment for each should be performed. 3. Review of personnel records for Personnel 4 revealed a competency assessment for the duties of General Supervisor was not performed in 2017. 4. In interview on May 22, 2018, Personnel 4 confirmed the laboratory did not perform a competency assessment for his duties as General Supervisor.

D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review and inteview with personnel, the laboratory failed to ensure the collection time for samples received from outside facilities was entered accurately for the two (2) of six (6) patients reviewed. Findings: 1. Review of the laboratory's "Requests for Laboratory Services" policy revealed "When a specimen is collected by nursing service or respiratory department, the date and time of collection and initials of the collector must be placed on the request and the properly labeled specimen tube. The laboratory personnel then writes the time the specimen is received into the lab." 2. Review of patient test requisitions and final reports revealed the laboratory did not accurately enter the collection times of patient samples into the Laboratory Information System (LIS) for the following two (2) of six (6) Home Health patients: a. Patient 1: collection time on the test requisition - Collection Time 15:00 collection time on the LIS final report - Collected Time 16:26 b. Patient 2: collection time on the test requisition - Collection Time 12:40 collection time on the LIS final report - Collection Time 12:10 3. In interview on May 24, 2018 at 3:55 pm, Personnel 4 stated the collection date and time on lab reports are supposed to match that of the requisition. Personnel 4 confirmed the above patients collection time was entered incorrectly.
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 centrifuged and separated from the cells within fifteen (15) minutes and analyzed promptly as required by the manufacturer. Findings: 1. Observation by the surveyor on May 21, 2018 revealed the laboratory was performing Lactic Acid testing on the Siemens Dimension Xpand Plus Chemistry analyzer. 2. Review of the Siemens Dimension Lactic Acid package insert revealed under "Specimen Collection and Handling" that specimens are to be centrifuged and plasma is to be separated from the cells within fifteen (15) minutes from collection and analyzed promtly. 3. In interview on May 24, 2018 at 8: 55 am, Personnel 4 stated the result time listed on the report given to surveyors indicates the collection time and that he wrote the completion time on the report. 4. Review of the report of patient records given to surveyors for Lactic Acid from February 22, 2018 through May 22, 2018 revealed the laboratory did not maintain documentation of the receipt times to ensure plasma was separated from blood cells

within fifteen minutes (15) for the following twenty six (26) patients: On May 6, 2018 Patient 3 was collected at 17:45 pm, no documentation of the receive time, result time of 18:47 pm -- total of sixty two (62) minutes from collection time to result time On March 31, 2018 Patient 4 was collected at 5:25 am, no documentation of the receive time, result time of 6:08 am -- total of forty three (43) minutes from collection time to result time On March 25, 2018 Patient 5 was collected at 19:20 pm, no documentation of the receive time, result time of 20:00 pm -- total of forty (40) minutes from collection time to result time On March 22, 2018 Patient 6 was collected at 17:00 pm, no documentation of the receive time, result time of 17:32 pm -- total of thirty two (32) minutes from collection time to result time On March 17, 2018 Patient 7 was collected at 22:13 pm, no documentation of the receive time, result time of 22:56 pm -- total of forty three (43) minutes from collection time to result time On February 26, 2018 Patient 8 was collected at 9:05 am, no documentation of the receive time, result time of 9:47 am -- total of forty two (42) minutes from collection time to result time On March 1, 2018 Patient 9 was collected at 6:40 am, no documentation of the receive time, result time of 7:08 am -- total of twenty eight (28) minutes from collection time to result time On March 17, 2018 Patient 10 was collected at 4:55 am, no documentation of the receive time, result time of 5:39 am -- total of forty four (44) minutes from collection time to result time On March 26, 2018 Patient 11 was collected at 4:40 am, no documentation of the receive time, result time of 5:18 am -- total of thirty eight (38) minutes from collection time to result time On April 2, 2018 Patient 12 was collected at 00:20 am, no documentation of the receive time, result time of 1:57 am -- total of one (1) hour thirty seven (37) minutes from collection time to result time On April 8, 2018 Patient 13 was collected at 22:15 pm, no documentation of the receive time, result time of 22:54 pm -- total of thirty nine (39) minutes from collection time to result time On April 28, 2018 Patient 14 was collected at 06:00 am, no documentation of the receive time, result time of 08:30 am -- total of two (2) hours thirty (30) minutes from collection time to result time On March 25, 2018 Patient 15 was collected at 09:06 am, no documentation of the receive time, result time of 09:42 am -- total of thirty six (36) minutes from collection time to result time On May 1, 2018 Patient 17 was collected at 10:40 am, no documentation of the receive time, result time of 11:22 am -- total of forty two (42) minutes from collection time to result time On April 4, 2018 Patient 18 was collected at 08:00 am, no documentation of the receive time, result time of 10:32 am -- total of two (2) hours thirty two (32) minutes from collection time to result time On March 13, 2018 Patient 19 was collected at 23:10 pm, no documentation of the receive time, result time of 23: 57 pm -- total of forty seven (47) minutes from collection time to result time On March 16, 2018 Patient 20 was collected at 14:10 pm, no documentation of the receive time, result time of 14:42 pm -- total of thirty two (32) minutes from collection time to result time On February 24, 2018 Patient 21 was collected at 23:55 pm, no documentation of the receive time, result time of February 25, 2018 at 00:30 am -- total of thirty five (35) minutes from collection time to result time On April 3, 2018 Patient 22 was collected at 21:30 pm, no documentation of the receive time, result time of 22:06 pm -- total of thirty six (36) minutes from collection time to result time On April 1, 2018 Patient 23 was collected at 00:15 am, no documentation of the receive time, result time of 00:41 am -- total of forty one (41) minutes from collection time to result time On March 30, 2018 Patient 24 was collected at 02:30 am, no documentation of the receive time, result time of 04:45 am -- total of two (2) hours fifteen (15) minutes from collection time to result time On March 15, 2018 Patient 25 was collected at 14:15 pm, no documentation of the receive time, result time of 15:25 pm -- total of one (1) hour ten (10) minutes from collection time to result time On April 23, 2018 Patient 26 was collected at 22:10 pm, no documentation of the receive time, result time of 23:10 pm -- total of one (1) hour from collection time to result

	time 5. In interview on May 24, 2018, Personnel 4 confirmed the laboratory could not ensure patient samples for Lactic Acid testing were centrifuged and separated from the cells within fifteen (15) minutes and analyzed promptly as required by the manufacturer.
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 D5401. 2. The laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Refer to D5411. 3. The laboratory failed to have complete verification studies for Troponin testing. Refer to D5421. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal mean Prothrombin Time (PT) with each new lot of Thromboplastin. Refer to D5545. 5. The laboratory failed to have a system in place for twice a year comparison testing for Troponin testing performed on the Abbott iSTAT. Refer to D5775. 6. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783. 7. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's records revealed the laboratory did not have written policies and procedures that included: a) Quality Control (QC): laboratory practices in place for each specialty to include the QC material in use, frequency of testing QC, review of QC results, whether an Individualized Quality Control Plan (IQCP) was performed, and notification of personnel when changes occur with each QC specialty. b) System in place to capture actual specimen collection and receipt date/time to ensure the quality of testing. 2. In interview on May 22, 2018, Personnel 4 confirmed the laboratory did not have the above policies in place.

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: **Repeat Deficiency from December 1, 2016** Based on observation, record review, and interview with personnel, the laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2018 revealed the laboratory utilizes the Abbott Cell-Dyn Ruby Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's policy for CBC's revealed "Using the following CBC screening criteria, determine if an automated differential is sufficient, or other manual reviews are indicated. All instrumentation flags on the automated differential are to be reviewed and solved before the automated differential is reported. If other reviews are indicated please refer to Manual Leukocte Procedure in this manual." 3. Review of the Cell-Dyn Ruby Operator's manual revealed the following messages and actions for flags: a) Var Lym*: Review a stained smear for the presence of variant lymphocytes and follow your laboratory's review criteria. b) Band*: Review a stained smear for the presence of bands and follow your laboratory's review criteria 4. Review of the laboratory's "Hematology Decision Rules--Cell Dyn Ruby" revealed the following messages and actions for flags: a) Band: Review smear for the presence of bands, as bands may be present >12.5% of the total WBC count or the ratio of suspected bands to mature neutrophils is >50%. Included in total neutrophil count. b) Var Lym: Review smear for presence of variant lymphs. Included in lymphocyte category. c) Monos >14%: Perform Manual Differential 5. Review of the laboratory's patient testing for CBCs and the instrument printouts in April 2018 revealed the following three (3) of thirty one (31) patients reported without addressing flags: a) On April 1, 2018 Patient 27 was run at 5:25 am with a Mono % result of 19.2% - No Manual Differential (to perform manual differential if Mono% >14%) b) On April 5, 2018 Patient 28 was run at 17:24 pm with a BAND flag - No smear review (to review smear for presence of bands) c) On April 7, 2018 Patient was run at 06:08 am with a VAR LYM flag - No smear review (to review smear for presence of variant lymphs) 6. In interview on May 24, 2018 at 15:02 pm, Personnel 9 stated he follows the "Hematology Decision Rules" and performs a manual differential for all flags. Personnel 9 further stated other testing personnel rerun flags before performing a slide review or manual differential. 7. In interview on May 24, 2018, Personnel 4 confirmed the above patients were resulted without following the manufacturer's instructions for flags. 8. Review of the Task 1 & 3 form given to surveyor on site revealed the laboratory performs 26,530 CBC's annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have complete verification studies for Troponin testing. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2018 revealed the laboratory utilizes the Abbott iStat analyzer for Troponin testing. 2. In interview on May 22, 2018 at 5:10 pm, Personnel 4 stated Troponin was ran on the iSTAT analyzer only for backup testing since October 2017. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did have a policy for performance verification studies. 4. Review of the laboratory's performance verification studies for Troponin testing on the iSTAT revealed the laboratory performed accuracy, precision, reportable and reference range studies; However, the Laboratory Director did not approve and sign off on the studies. 5. In interview on May 23, 2018 at 3:00 pm, Personnel 4 stated the Troponin method validation was reviewed by the Laboratory Director. Personnel 4 further stated he thought since the Laboratory Director reviewed and signed off on the policy and procedure for Troponin that it was acceptable. 6. In further interview on March 23, 2018, Personnel 4 confirmed the Laboratory Director did not sign off on the method validation study for Troponin. 7. Review of the laboratory's Task 1 & 3 forms revealed the laboratory performs twenty (20) Troponin tests annually on the iSTAT analyzer.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal mean Prothrombin Time (PT) with each new lot of Thromboplastin. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2018 revealed the laboratory utilized a Sysmex CA 540 analyzer and Siemens Dade Innovin (Thromboplastin reagent) for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the laboratory's coagulation policy and procedure manual revealed "New lots of reagents for prothrombin time and PTT must have a normal population study done to verify the normal range before putting into use. The normal donors must sign questionnaires attesting the donor is healthy and not on any of several specified medications"; However, the laboratory did not define the "normal" donor criteria in their policy 3. Review of manufacturer's instructions for establishment of reference interval revealed the following requirements for "normal donors": a. Donors must be from a healthy population (no known pathological condition) b. Donors should not take any medications, including aspirin. c. A minimum of 20 donors with reasonably even distribution of males and females should be included. d. Donors should span adult age ranges. (NOTE: A separate range should be established for pediatric populations) e. Testing should be performed over a period of several days and by different people, if possible, to minimize day to day variation.

	f. A minimum of 4-6 specimens should be drawn each testing day, following the established laboratory protocol for collection, storage and processing of patient plasma samples. 4. Review of the most recent change in lot number for Innovin (Lot 549708 Exp 2/23/20) revealed the laboratory calculated a new normal PT mean and verified the reference interval by using twenty eight (28) "normal" patient results. The value was compared to the previous lot number of Innovin (Lot 539353A Exp 4/28 /18); However, the laboratory did not ensure these individuals met the above criteria required by the manufacturer of normal donors. 5. Further review of the Normal Mean PT study revealed the laboratory did not ensure the "normal" donors utilized in the study met the acceptable criteria as required by the manufacturer for the following two (2) of twenty eight (28) donors reviewed: a) Patient 30 -- taking aspirin (per reference study questionaire) b) Patient 31 -- taking birth control (per reference study questionaire) 6. In interview on May 23, 2018 at 11:04 am, Personnel 4 stated the laboratory did not have a policy stating the criteria for normal donors. Personnel 4 confirmed the above normal donors were utilized in the normal mean PT study. 7. Review of the laboratory's Task 1 & 3 form revealed the laboratory performs 1,510 PT /INR tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place for twice a year comparison testing for Troponin testing performed on the Abbott iSTAT. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2018 revealed the laboratory utlizes the Siemens Dimension Xpand Plus and the Abbott iSTAT for Troponin testing. 2. In interview on May 21, 2018 during the laboratory tour, Personnel 4 stated the Abbott iSTAT is utilized as the back-up analyzer for Troponin testing. 3. Review of the laboratory's policy manual revealed the laboratory did not have a procedure for the annual comparison for the Siemens Dimension Xpand Plus and the Abbott iSTAT Troponin testing. 4. In interview on May 23, 2018 at 12:17 pm, Personnel 4 stated the laboratory will run American Proficiency Institute (API) samples that were previously performed on the Siemens Dimension Xpand Plus but there is not a detailed, written policy stating this. 5. Review of the Task 1 & 3 form revealed the laboratory performs twenty (20) Troponin tests annually on the Abbott iSTAT.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of

	accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2018 revealed the laboratory utilizes the Siemens Dimension Xpand Plus analyzer for Chemistry testing. 2. Review of the laboratory's "Quality Control Policy and Procedures" revealed "Two levels (normal and abnormal) of QC products, Multiqual 1 & 3, Immunoassay levels 1 & 3 and Bio Rad Cardiac Markers levels 1 & 3 are performed once every twenty four hours after the morning system check, approximately 0900." 3. Further review of the laboratory's "Quality Control Policy and Procedures" under "Corrective action steps for QC" revealed the following: 1. Repeat the same QC material, if still unacceptable 2. Repeat using new QC material, if still out 3. Contact supervisor or call technical support 4. Review of the "Chemistry Quality Control Corrective Action" policy revealed under "Troubleshooting Quality Control" the following suggestions for addressing QC: make sure you are using the correct control product/lot number and rerun the QC using a fresh vial of QC material. 5. Review of the laboratory's Quality Control (QC) data for April 2018 revealed the laboratory performed Serum QC1 testing for the following tests (Aspartate Aminotransferase (AST), Amylase (AMY), Alanine Transaminase (ALT), Blood Urea Nitrogen (BUN), Calcium (CA), Lactic Acid (LA), Creatinine (CREA), Creatine Kinase (CK), Total Protein (TP), Total Bilirubin (TBI), Phosphorus (PHOS), Carbon Dioxide (CO2), Lipase (LIP), Magnesium (MG), Glucose (GLUC), Sodium (NA), Potassium (K), Chloride (CL), Albumin (ALB), Alkaline Phosphatase (ALP), and Troponin (TNI)) on April 14, April 15, and April 16: However, the records showed multiple results for those days. 6. Further review of the laboratory's Quality Control (QC) data for April 2018 revealed the laboratory did not have documentation of performing Serum QC3 on April 14 and April 15. 7. In interview on May 22, 2018 at 2:05 pm, Personnel 4 stated the testing personnel ran the QC in the wrong file for the above dates. Personnel 4 further stated if the wrong QC file is ran then it is common knowledge to repeat with the correct QC material. 8. In further interview on May 22, 2018 at 3:15 pm, Personnel 4 stated that if QC is run in wrong QC file then results are evaluated for the proper level and accepted without repeating. 9. In interview on May 22, 2018 at 3:23 pm, Personnel 14 stated if QC is run in the incorrect file then she reruns in the correct file and deletes the incorrect data and writes information in the corrective action log. 10. Review of the laboratory's patient records for April 2018 revealed the following patients were reported without two levels of acceptable QC results: On April 14, 2018 - Patients 32 -45 On April 15, 2018 - Patients 47 - 56 11. Review of the laboratory's "Chemistry QC Corrective Action Log" revealed documentation of the laboratory performing Serum QC3 in the wrong QC file on April 14, 2018 and that the results were checked against the Serum QC3 ranges and accepted without repeating. 12. Further review of the "Chemistry QC Corrective Action Log" revealed the laboratory did not document corrective action for April 15, 2018 and April 16, 2018 pertaining to wrong QC file being used. 13. In interview on May 23, 2018, Personnel 4 stated he thought writing error beside the QC files for Chemistry was acceptable. Personnel 4 further stated since the instrument was fine and QC values were acceptable in the correct files then everything was fine.
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 observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Refer to D5411. 3. The laboratory failed to have complete verification studies for Troponin testing. Refer to D5421. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal mean Prothrombin Time (PT) with each new lot of Thromboplastin. Refer to D5545. 5. The laboratory failed to have a system in place for twice a year comparison testing for Troponin testing performed on the Abbott iSTAT. Refer to D5775. 6. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783.
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 that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 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 that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 5. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 6. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 7. 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.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure the collection time for samples received from outside facilities was entered accurately for the two (2) of six (6) patients reviewed. Refer to D5309. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing are centrifuged and separated from the cells within fifteen (15) minutes and analyzed promptly as required by the manufacturer. Refer to D5311. 3. The laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Refer to D5411. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal mean Prothrombin Time (PT) with each new lot of Thromboplastin. Refer to D5545.
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.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5775.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.
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 established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209, D6054, and D6128.
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 D5401.
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 observation, record review and interview with personnel, the Technical Consultant failed to provide oversight for the laboratory. 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 performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6044. 4. The Technical Consultant failed to evaluate and document personnel competenct annually for eight (8) of eight (8) testing personnel reviewed. Refer to D6054.
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 the collection time for samples received from outside facilities was entered accurately for the two (2) of six (6) patients reviewed. Refer to D5309. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing

	are centrifuged and separated from the cells within fifteen (15) minutes and analyzed promptly as required by the manufacturer. Refer to D5311. 3. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 4. The laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC). Refer to D5411. 5. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal mean Prothrombin Time (PT) with each new lot of Thromboplastin. Refer to D5545. 6. The laboratory failed to have a system in place for twice a year comparison testing for Troponin testing performed on the Abbott iSTAT. Refer to D5775.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document personnel competenct annually for eight (8) of eight (8) testing personnel reviewed. Findings: 1. Reviw of the laboratory's 2016 personnel records revealed the Technical Consultant performed competency assessments on testing personnel; However, the competency assessments did not include all the laboratory specialties. 2. Review of the laboratory's 2017 personnel records revealed the Technical Consultant did not perform competency assessments for the following personnel performing moderate complexity testing: Personnel 5 Personnel 6 Personnel

	7 Personnel 8 Personnel 10 Personnel 11 Personnel 13 Personnel 14 3. In interview on May 22, 2018, Personnel 4 stated that he and the Laboratory Director had updated the personnel competency assessment policy to include all the specific parts needed. Personnel 4 further stated that he had performed the 2018 competency assessments according to the updated policy.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to evaluate and document personnel competency annually for eight (8) of eight (8) personnel reviewed. Findings: 1. Review of the 2017 personnel records on May 22, 2018 revealed the Technical Supervisor (Personnel 4) failed to perform competency assessments for the following eight (8) of eight (8) personnel performing high complexity testing: Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 10 Personnel 11 Personnel 13 Personnel 14 2. In interview on May 22, 2018, Personnel 4 confirmed annual competency assessments were not performed for 2017.