Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1094011	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Caddo Medical Center	815 South Pine St, 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 (RESP) - CLIA # 19D1094011 on May 21, 2018 through May 25, 2018. The laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. 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 in the specialty of Routine Chemistry. Findings: 1. The laboratory failed to include the specimen collection time for Arterial Blood Gas testing. Refer to D5305. 2. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to ensure quarterly maintenance for the Opti-CCA was performed and documented as required. Refer to D5429. 4. The laboratory failed to perform Quality Controls every thirty (30) days as required by the Individulized Quality Contol Plan (IQCP) for Arterial Blood Gas testing. Refer to D5445. 5. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Routine Chemistry. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for the Clinical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 16 serves as the laboratory's Clinical Consultant. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Clinical Consultant. 3. Review of personnel records for Personnel 16 revealed a competency assessment for duties as Clinical Consultant was not performed. 4. In interview on May 22, 2018 at 11:26 am , Personnel 1 stated the laboratory did not have a policy and there is not a competency assessment for Personnel 16's duties as Clinical Consultant.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to document the specimen collection time for Arterial Blood Gas testing. Findings: 1. Observation by surveyors during laboratory tour on May 21, 2018 revealed the laboratory utilizes the Opti CCA-TS2 analyzer for Arterial Blood Gas (ABG) testing. 2. Review of the Opti CCA-TS2 procedure manual revealed "Whole blood samples should be collected in a heparinized syringe, ComfortSampler, or capillary and analyzed as soon as possible, ideally within 5 minutes after collection." 3. Review of the laboratory's Sampling Procedure revealed "The specimen must be tested as soon as possible after collection and within the time frame specified in the testing method." 4. Review of patient records revealed the laboratory did document the analyze time; However, they did not document the actual collection time for the following patients: Patients 39 - 59 5. In interview on May 22, 2018 at 11:37 am, Personnel 2 stated the testing personnel writes the collection time on the samples but does not document them anywhere else. Personnel 2 confirmed the specimen collection times were not included for the above patients.
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 ensure the procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies that included the following: a) Step-by-step performance of the procedure, to include collection, receive and result times for Blood Gas testing. b) Quality Control (QC) to include the current practices in place. 2. In interview on May 22, 2018 at 9:00 am, Personnel 2 stated the current policy manual did not include the laboratory's current collection process and QC practices.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Opti-CCA was performed and documented as required. Findings: 1. Review of the "Opti-CCA Maintenance Logs" indicated the following quarterly maintenance task: Quarterly: "Perform tHb-Calibration" 2. Further review of the 2017 Opti-CCA maintenance logs revealed the laboratory did not document quarterly maintenance for the following three (3) of four (4) quarters: 1st Quarter, due March 2017 2nd Quarter, due June 2017 3rd Quarter, due September 2017 3. In interview on May 21, 2018 at 4:50 pm, Personnel 18 stated the previous department head for Respiratory (Personnel 17) did not require testing personnel to perform quarterly maintenance (tHB-Calibration) for the first three quarters of 2017 due to the laboratory not reporting Hgb results on ABG reports. 4. In interview on May 21, 2018 at 4:55 pm, Personnel 2 stated she took over as the Respiratory Department Head in October 2017 and decided the start performing the quarterly maintenance in

	December 2017. Personnel 2 confirmed the laboratory did not perform quarterly maintenance as required.
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 perform Quality Controls every thirty (30) days as required by the Individulized Quality Contol Plan (IQCP) for Arterial Blood Gas testing. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2018 revealed the laboratory utilizes the Opti CCA-TS2 analyzer for Arterial Blood Gas (ABG) testing. 2. Review of the laboratory's IQCP records revealed the laboratory is to perform Liquid Quality Control (QC) every thirty (30) days (monthly). 3. Review of patient records from January 2017 through April 2018 revealed the following patients resulted without QC performed: * March 2, 2017 through March 7, 2017 (QC performed February 2, 2017 then not again until March 8, 2017) Patients 1 - 6 * July 9, 2017 through July 12, 2017 (QC performed June 9, 2017 then not again until July 14, 2017) Patients 7 - 9 * September 9, 2017 through September 15, 2017 (QC performed August 9, 2017 then not again until September 16, 2017) Patients 10 - 19 * October 16, 2017 through November 1, 2017 (QC performed September 16, 2017 then not again until November 2, 2017) Patients 20 - 38 * April 2, 2018 through April 13, 2018 (QC performed March 2, 2018 then not again until April 14, 2018) Patient 39 - 59 4. In interview on May 21, 2018 at 4:18 pm, Personnel 2 stated the laboratory runs liquid controls on the 2nd day of each month. Personnel 2 confirmed the QC was not performed every 30 days (monthly) per IQCP policy.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Routine Chemistry. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to include the specimen collection time for Arterial Blood Gas testing. Refer to D5305. b) The laboratory failed to ensure the procedure manual contained complete policies and procedures.

	Refer to D5403. c) The laboratory failed to ensure quarterly maintenance for the Opti-CCA was performed and documented as required. Refer to D5429. d) The laboratory failed to perform Quality Controls every thirty (30) days as required by the Individulized Quality Contol Plan (IQCP) for Arterial Blood Gas testing. Refer to D5445. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with Personnel 1 and 2 on May 22, 2018 confirmed the above findings.
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 for accurate and reliable results. 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 that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6023. 5. 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. 6. 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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5305.
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. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on 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 D5791.
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 D5429.
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.
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.