Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463303	01/29/2021
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 on January 25, 2021 through January 29, 2021 at North Caddo Medical Center, CLIA ID # 19D0463303. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies did not exceed their expiration dates. Findings: 1. Direct observation by surveyor during laboratory tour on January 25, 2021 at 1:20 pm revealed the following expired items: a) Mayo Clinic Covid Testing Media T846; Lot 062520-4; Expiration 12/25/2020; Quantity sixteen (16) 3mL vials 2. In interview on January 25, 2021 at 1:25 pm, Personnel 8 stated the media vials were used with the original send out Covid testing and discontinued in October 2020 since the laboratory no longer sends specimens using this media. Personnel 8 confirmed the media vials were expired.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the laboratory failed to document positive and negative controls for Serum Acetone testing for two (2) of twenty nine (29) patients reviewed. Findings: 1. Review of the laboratory's "Clinitest, Ketone, & Ictotest QC Log" revealed "Ketone QC performed when opening a new bottle of reagent and every 24 hours of patient testing". 2. Review of patient records and quality control (QC) logbook from January 2020 through December 2020 revealed the laboratory did not document external positive and negative controls each day of patient testing for the following two (2) of twenty nine (29) patients reviewed: a) Accession 27-20-049-00035 performed February 18, 2020 at 05:36 am b) Accession 27-20-072-00051 performed March 12, 2020 at 05:30 am 3. In interview on January 28, 2021 at 10:17 am, the General Supervisor confirmed external QC was not performed for each of the above cited patients. 4. Review of the task 1&3 form provided by staff revealed the laboratory performs thirty (30) Serum Acetone tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate 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 perform corrective actions when the cuvette temperature was not within acceptable range as required by the manufacturer for the Siemens Dimension EXL 200 Chemistry analyzer. Findings: 1. Observation by surveyor during laboratory tour on January 25, 2021 at 1:20 pm revealed the laboratory utilizes the Siemens Dimension EXL 200 analyzer for Chemistry testing. 2. Review of the Siemens Dimension EXL 200 Chemistry analyzer maintenance logs revealed the acceptable cuvette temperature range as 36.8 to 37.2 degrees Celsius. 3. Further review of the laboratory's maintenance logs from August 2020 through December 2020 revealed the laboratory did not take corrective action when the cuvette temperature was out of acceptable range for the following three (3) of one hundred fifty three (153) days reviewed.: a) October 18, 2020 -- temperature recorded as 36.7 degrees celsius b) October 23, 2020 -- temperature recorded as 36.7 degrees celsius c) November 13, 2020 -- temperature recorded as 36.7 degrees celsius 4. In interview on January 28, 2021 at 9:15 am, the Laboratory Supervisor stated he could not find Quality Assurance (QA) or corrective actions for the above unacceptable temperatures. The Laboratory Supervisor further stated he missed seeing these unacceptable temperatures during his monthly QA checks.

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 direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5417.
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 a quality control program was maintained to assure quality laboratory services were provided. Refer to D5449.
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 observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5417.
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 established to assure the quality of laboratory testing. Refer to D5449.