Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464390	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
West Carroll Medical Clinic	502 Ross Street, Oak Grove, 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 conducted June 28, 2018 at West Carroll Medical Clinic - CLIA ID # 19D0464390. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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 observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on June 28, 2018 revealed the following expired items: * Cabinet located in laboratory: a) two (2) purple microtainers - Lot 15H4004 Exp 08 /17 * Phlebotomy Tray located on laboratory counter a) eight (8) purple microtainers - Lot 15C4238 Exp 04/17 b) four (4) purple microtainers - Lot 15K4044 Exp 11/17 c) ten (10) purple microtainers - Lot 15H4044 Exp 08/17 d) three (3) purple microtainers - Lot 12I4060 Exp 11/14 e) one (1) purple microtainer - Lot 14K4166 Exp 12/16 f) one (1) purple microtainer - Lot 13K4385 Exp 01/16 g) one (1) purple microtainer - Lot 13F4411 Exp 07/15 2. In interview on June 28, 2018 at 9:40 am, Personnel 2 stated she was unaware of expired supplies. Personnel 2 confirmed the supplies were expired.
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 verify the means for Quality Control (QC) material for Hematology testing prior to use. Findings: 1. Observation by surveyor during laboratory tour on June 28, 2018 revealed the laboratory utilizes the Horiba ABX Micros 60 analyzer with Horiba Medical Minotrol 16 Tri-Level Controls for Complete Blood Count (CBC) testing. 2. Review of the Minotrol 16 Tri-Level Controls package insert under "Performance and characteristics" section revealed "Assay values on a new lot of control should be confirmed before it is put into routine use. The laboratory recovered mean should be within the assay range." 3. Review of the laboratory's policy and procedure manual revealed the laboratorydid have a policy for the new lots of controls which stated "Verification of QC ranges given should be done prior to putting a new lot in use." 4. Review of the laboratory's QC records revealed the laboratory did not have documentation of verification of new lot QC means prior to use or runs concurrent with previous lot for the following lot numbers: Lot # MX409 Exp 3/5/18 Lot # MX410 Exp 5/5/18 Lot # MX411 Exp 7/5/18 5. In interview on June 28, 2018 at 10: 30 am, Personnel 2 stated the testing personnel should be verifying controls but she could not find any documentation to support. Personnel 2 confirmed the laboratory did not verify the means for new lots of QC.
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 record review and interview with personnel, the laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Findings: 1. Review of the laboratory's Quality Assurance (QA) form revealed the laboratory did have a Hematology QA monitor in place for Lot to Lot verification; However, the monitors did not identify and correct the issue for the following: a) The laboratory failed to verify the means for Quality Control (QC) material for Hematology testing prior to use. Refer to D5469. 2. In interview on June 28, 2018 at 11:45 am, Personnel 2 confirmed the QA monitors in place did not correct the above issues.
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 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 D5791.