Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2045763	04/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Coughran Medical Group	101 Fair Avenue, Winnsboro, 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 on April 16, 2018 at Coughran Medical Group - CLIA ID # 19D2045763. 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 calibrators and blood collection tubes have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on April 16, 2018 revealed the following expired items: a. Two (2) 2.5 ml vials Cell Dyn 18 Plus Calibrator Lot 80430 Exp 03-28-2018 b. One (1) Purple top microtainer Lot 6137925 Exp 10-2017 2. In interview on April 16, 2018, Personnel 2 and 3 confirmed the above were expired and in place for testing.
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 hematology testing. Findings: 1. Observation by surveyors during laboratory tour on April 16, 2018 revealed the laboratory utilizes an Abbott Cell Dyn Emerald analyzer with Cell Dyn 18 Plus quality controls for Complete Blood Count (CBC) testing. 2. Review of the manufacturer's package insert for the Cell Dyn 18 Plus controls under "Performance Characteristics" revealed "The mean assay values are derived from repetitive testing on several instruments operated and maintained according to the manufactuter's instructions; they do not necessarily apply to a single instrument. The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus they are wider than the +/-2 SD QC range for one instrument". 3. Review of the laboratory's QC records from April 2017 through April 2018 revealed the following Cell Dyn 18 Plus Hematology Controls utilized without establishment of means and ranges: a. Lot 8071 (L, N, H) Exp 6/29/18 - Put in use 4 /11/18 b. Lot 7268 (L, N, H) Exp 1/12/18 - Put in use 9/27/17 c. Lot 7156 (L, N, H) Exp 9/22/17 - Put in use 7/25/17 d. Lot 7100 (L, N, H) Exp 7/28/17 - Put in use 4/12 /17 3. In interview on April 16, 2018 at 2:32 pm, Personnel 2 stated the laboratory utilizes the manufacturer's means and ranges and that he was unaware that QC needed to be established. 4. Review of the Task 1 & 3 form provided to surveyors by personnel revealed the laboratory performs one thousand six hundred (1600) CBCs annually.
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 the laboratory personnel were performing test methods as required for accurate and reliable results. 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 the quality control was maintained to assure quality laboratory services were provided. Refer to D5469.