Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2045763	08/23/2022
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 Recertification survey was performed on August 23, 2022 at Coughran Medical Group, CLIA ID # 19D2045763. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures for waived testing and interview with personnel, the laboratory failed to have a complete policy and procedure for the reporting of SARS CoV-2 test results to the appropriate state agency. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include the following written policy: a) Written, detailed instructions for the reporting of SARS CoV-2 test results to the state public health agency, to include but not limited to who is responsible for reporting test results and the frequency at which reporting is performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's operator manual, laboratory's temperature logs and interview with personnel, the laboratory failed to document the room temperature where laboratory instrumentation are maintained. Findings: 1. Observation by surveyor during the laboratory tour on August 23, 2022 revealed the laboratory utilizes the following instrumentation for patient testing: a) Sysmex XP-300 Hematology analyzer b) Beckman Coulter Access 2 Chemistry analyzer 2. Review of the manufacturer's operator manual for Hematology and Chemistry instruments maintained in the laboratory revealed the following environmental conditions: a) Sysmex XP-300: ambient temperature of 15-30 degrees celsius (59-86 degrees fahrenheit) b) Beckman Coulter Access 2: ambient temperature of 18-28 degrees celsius (64-82 degrees fahrenheit) 3. Review of the laboratory's temperature records for January 2021 through July 2022 revealed the laboratory documents the room temperature each day of patient testing with an acceptable range of 20-32 degrees celsius/68-89.6 degrees fahrenheit. 4. Further review of the laboratory's temperature records for January 2021 through July 2022 revealed the laboratory did not document the room temperature for the following two (2) of nineteen (19) months reviewed: a) November 2021 b) December 2021 5. In interview on August 23, 2022 at 10:46 am, Testing Personnel 2 stated that something spilled onto the temperature logs and the logs were not legible. Testing Personnel 2 further stated the temperature logs were rewritten using the information from the original logs and the room termperature values were not carried over to the new documentation. 6. In further interview on August 23, 2022 at 10:46 am, Technical Consultant stated that he missed the room temperature documentation upon his monthly quality assurance checks. Technical Consultant confirmed the identified room temperture records were not documented as required.
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 by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
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 by surveyor, review of laboratory policy and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5413.