

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2045763	(X3) Date Survey Completed 12/11/2020
Name of Provider or Supplier Coughran Medical Group	Street Address, City, State 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 performed on December 11, 2020 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.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Performance specification: detailed procedures for performing accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on December 11, 2020 at 11:53 am, the Technical Consultant confirmed the above policy was not included in the laboratory policy and procedure manual.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

I. Based on observation, record review and interview with personnel, the laboratory failed to have complete precision studies for the Beckman Coulter Access 2 Chemistry analyzer. Findings: 1. Observation by surveyor during the laboratory tour on December 11, 2020 at 9:45 am revealed the laboratory utilizes the Beckman Coulter Access 2 Chemistry analyzer for patient testing for the following tests: Free Triiodothyronine (FT3), Free Thyroxine (FT4), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), Testosterone, Vitamin B12, and Vitamin D. 2. Review of the laboratory's data revealed the following studies performed on the Beckman Coulter Access 2: a) Method Comparison for accuracy b) Simple Precision c) Linearities for Reportable Range d) Reference Range 3. Further review of the laboratory's data revealed the following data was not included: a) Complete Precision to include Day to Day and Operator Variance 4. In interview on December 11, 2020 at 12:26 pm, the Technical Consultant stated that testing personnel participated in the studies but did not document the day to day and operator variance parts performed. II. Based on observation, record review and interview with personnel, the laboratory failed to have complete precision studies for the Sysmex XP 300 Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on December 11, 2020 at 9:45 am revealed the laboratory utilizes the Sysmex XP 300 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's data revealed the following studies performed: a) Method Comparison for accuracy b) Simple Precision c) Reportable Range d) Reference Range 3. Further review of the laboratory's data revealed the following was not included: a) Complete Precision to include Day to Day and Operator Variance 4. In interview on December 11, 2020 at 11:53 am, the Technical Consultant stated the above information was not included with the performance studies.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421 I and II.

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. Refer to D5401.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421 I and II.