

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0702977	(X3) Date Survey Completed 03/20/2019
Name of Provider or Supplier Rockdale Family Practice	Street Address, City, State 2020 Honey Creek Parkway, Conyers, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 20, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interviews with the laboratory coordinator and clinic administrator, the laboratory failed to implement and established safety procedure to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. During the laboratory tour it was observed there was not a maintenance log for the eyewash equipment in the laboratory testing area. 2. An interviews with the laboratory coordinator and clinic administrator during the laboratory tour on 03/20 /2019 at approximately 10:30 a.m. confirmed the eyewash equipment had no maintenance log.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of policy and procedure manual, laboratory tour and staff interview, the laboratory failed to include a policy or chart dealing with panic or alert values in laboratory testing of patient samples. Findings include: 1.) Procedure manual review revealed no policy or chart for panic or alert values in the policy manual or on the wall in the laboratory. 2.) An interview the laboratory coordinator and clinic administrator in the review room at approximately 01:00 pm on 03/20/2019 confirmed there was no policy or chart for panic values in the procedure manual or in the laboratory.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the 2018 AAFP (American Academy of Family Physicians) Proficiency Testing(PT) documents and interviews with the laboratory coordinator and clinic administrator, the laboratory director failed to ensure Proficiency Testing results were submitted within the timeframes established by the PT program. Findings include: 1.) A review of the 2018 AAFP (PT) records revealed Event #A of the Hematology survey received a score of 0% "Failure to Participate" because results were not submitted to AAFP on a timely basis. 2.) An interview with the laboratory coordinator and clinic administrator, at approximately 12:15 pm on 03/20/2019 in the review room confirmed the laboratory failed to submit PT results before its cut off date.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance and Quality Assurance(QA) records and an interview with the laboratory coordinator, the Technical Consultant (TC) who is also the laboratory director failed to review and sign Monthly Quality Assurance report records in 2017, 2018 and 2019. Findings include: 1. Review of maintenance and Quality Assurance reports revealed QA logs were not reviewed and signed in 2017, 2018 and 2019 by the (TC). 2. An interview with the laboratory coordinator on 03/20/2019 at approximately 12:40 pm in the review room confirmed that maintenance QA reports were not reviewed and signed by the (TC) 2017, 2018 and 2019.