

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2167346	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier Erlanger Primary Care - Ringgold	Street Address, City, State 6982 Nashville Street, Ringgold, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on March 3, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to include requirements for specimen collection as required by CLIA (Clinical Laboratory Improvement Amendments). Findings include:</p>

1. SOP review revealed the lack of venous and capillary specimen collection policies and procedures. 2. An interview with Staff #2 (CMS 209) in a medical office on 3/3/2020 at approximately 12:45 p.m. confirmed the lack of the aforementioned policies and procedures.

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 analyzer operations manual review, maintenance document review, and staff interview, the laboratory failed to monitor laboratory environmental conditions as required by the manufacturer. Findings include: 1. AcT Diff 2 operations manual review revealed this analyzer operates at ambient temperature 61-95 degrees Fahrenheit and at a humidity no higher than eight five percent (85%). 2. Maintenance document review revealed there were no laboratory temperature and humidity logs for 2019 and 2020 thus far available at the time of survey. 3. An interview with Staff #2 (CMS 209) in a medical office on 3/3/2020 at approximately 12:30 p.m. confirmed the lack of temperature and humidity logs for 2019 and 2020 thus far.