

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2167346	(X3) Date Survey Completed 01/24/2024
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	A recertification survey was performed on January 24, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
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 procedure manual (SOP) review and a interview with the lab coordinator, the laboratory failed to have a policy for an inoperable test system Findings include:</p>

1. SOP review reveals the laboratory failed to have a written policy for an inoperable test system. 2. Interview with the lab coordinator on 01/24/24 at 11:20 a.m. in the breakroom confirmed the lack of the aforementioned procedure.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on lack of Beckman Coulter ACT Diff 2 maintenance documents and an interview with the lab coordinator, the laboratory failed to perform and document analyzer maintenance activities as required. Findings include: 1. ACT Diff 2 analyzer document review revealed there were no routine maintenance documents available at the time of survey for 2022, 2023, or 2024 thus far. 2. Interview with the lab coordinator on 1/24/2024 in the breakroom at 11:15 a.m. confirmed the lack of routine maintenance documentation for the ACT Diff 2 analyzer for the aforementioned dates.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on lab report review and interview with the lab coordinator, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings: 1. Review of in house test reports (02306182 and 02313797) revealed the lack of the testing lab's name and address. 2. Interview with the lab coordinator on 1/24/24 at 11:30 AM in the breakroom confirmed the aforementioned finding.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and an interview with the medical office supervisor, the technical consultant failed to perform semiannual competency on all testing personnel. Findings: 1. Review of TP competency records

revealed the lack of a semi annual competency on TP #3 (CMS 209). 2. Interview with the medical office supervisor on 01/24/24 at 11:30 am in the breakroom confirmed the aforementioned finding.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of testing personnel(TP) documents and interview with the medical office supervisor , the technical consultant failed to perform annual competency on all testing personnel. Findings: 1. Review of TP competency revealed the lack of competency documentation for 2023. Per Lab Corrective Action Form, "competencies were not completed for 2023". 2. Interview with the medical office supervisor on 1/24 /24 at 11:45 am in the breakroom confirmed TP competencies were not done in 2023.