

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2047639	<b>(X3) Date Survey Completed</b>  01/23/2024
<b>Name of Provider or Supplier</b>  Erlanger Ringgold South	<b>Street Address, City, State</b>  60 Erlanger South Drive, Ringgold, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was performed on January 23,2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Beckman Coulter ACT Diff 2 maintenance documents and testing personnel (TP) interview, 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 TP #1 (CMS 209) on 1/23/2024 in a vacant providers office at 11:45 a.m. confirmed the lack of routine maintenance documentation for the ACT Diff 2 analyzer for the aforementioned dates.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result</p>

reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on lack of Beckman Coulter ACT Diff 2 maintenance documents and testing personnel (TP) interview, the laboratory failed to perform and document analyzer background count activities as required. Findings include: 1. ACT Diff 2 analyzer document review revealed there were no daily analyzer background count documents available at the time of survey for the analyzer for 2022, 2023, or 2024 thus far. 2. Interview with TP #1 (CMS 209) on 1/23/2024 in a vacant providers office at 11:45 a. m. confirmed the lack of daily background count documents 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 Testing Personnel (TP) interviews, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings: 1. Review of in house test reports (02369699 and 03685427) revealed the lack of the testing lab's name and address. 2. Interviews with TP #1 and #2 (CMS 209) on 1/23/24 at 11:30 AM in a vacant providers office confirmed the aforementioned finding.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with the practice manager, the laboratory director (LD) failed to ensure testing personnel (TP) met the educational qualification requirements to perform moderate complexity testing. Findings include:

1. Review of personnel records revealed TP #4 (CMS 209) failed to present the required high school diploma, General Equivalency Diploma (GED), or college degree. 2. Interview with the practice manager on 01/23/24 at 11:30 AM in a vacant providers office, confirmed the the aforementioned finding.