Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2167346	04/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Erlanger Primary Care - Ringgold	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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 6, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff review, the laboratory failed to rotate personnel who routinely perform the testing in the laboratory. The Findings include: 1. College of American Pathologist (CAP) PT document review revealed that 1 testing personnel out of 2 testing personnel, performed 6 total Events for 2020 and 2021 (2020 and 2021: CAP Event 1, CAP Event 2, and CAP Event 3). 2. During an interview with Testing Personnel (TP) #2 (CMS 209) on April 6, 2022 at 12:15 PM, confirmed that the laboratory failed to rotate personnel for the PT in 2020 and 2021.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The general laboratory procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) for staff to follow when sending specimens to reference laboratories (Quest, and LabCorp). 2. During an interview, on April 6, 2022, at 1:00 PM, in the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratories.