Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0261043	05/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jenkins County Medical Center	931 East Winthrope Avenue, Millen, 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 May 10, 2023. 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:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The findings include: 1. Laboratory QA document review revealed the lack of a QA checklist for 2021 (January 2021- December 2021) and 2022 (January 2022-December 2022), and thus far 2023 (January-May 2023). 2. During an interview with the General Supervisor (CMS 209), on May 10, 2023 at 2:25 PM, in the breakroom, confirmed the lack of a QA checklist for 2021, 2022, and thus far 2023.
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. A review of the SOP confirmed that a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) was not available for staff to follow when sending specimens to a reference laboratories: CoreBio and Quest). 2. During an interview, on May 10, 2023 at 2:05 PM, with the General Supervisor (CMS-209), in the laboratory, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.