Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301897	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Greene County Health System	509 Wilson Avenue, Eutaw, AL	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the Biosite Triage Meter Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to retain the manufacturer's QC assay information sheets for control materials. This was noted from 6/18/2021 to 7/15/2022. The findings include: 1. A review of Biosite Triage Meter Cardiac and D-Dimer QC records revealed only instrument print outs were retained. The QC records did not include all manufacturer's assay sheets or documentation of acceptable ranges for each QC lot number. 2. During an interview on 08/10/2022 at 11:15 AM, Testing Personnel #1 confirmed the laboratory had not retained the manufacturer's assay sheets with acceptable QC ranges.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of personnel records, a review of the Policies and Procedures, and an interview with Testing Personnel #1, the laboratory failed to follow written policies and procedures to assess employee competency. This was noted for eight out of eight

	Testing Personnel from September 2020 to August 2022. The findings include: 1. A review of the personnel records revealed a lack of acceptable documentation of competency assessment for each employee. The "Annual Evaluation" form in use evaluated performance overall as a hospital employee, not specifically assessing competency for moderate complexity testing performed within the laboratory. The form used for competency assessment did not evaluate all six competency assessment criteria as specified by CLIA. 2. A review of Policies and Procedure revealed the following under a section titled, "Laboratory Competency Program", "...A yearly competency assessment will be done including Survey participation, demonstration, simulation, observation, and CEU participation.". 3. During an interview on 08/10 /2022 at 12:01 PM, the surveyor reviewed and confirmed the above findings with Testing Personnel #1 and the Technical Consultant.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the patient and quality control (QC) records for Serum HCG (Human Chorionic Gonadotropin) and C. Diff (Clostridium difficile), and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure two levels of qualitative QC were performed each day of patient testing, in the absence of an IQCP (Individualized Quality Control Plan). Twelve days were noted between July 2021 and July 2022 when patient tests were performed with no documentation of QC. The findings include: 1. A review of patient records revealed the following: a) Serum hCG was performed on patients on 07/17/2021, 07/26/2021, 09/23/2021, 09/25/2021,10/08/2021, 11/20/2021, 12/22/2021, 01/28/2022, and 02/17 /2022. b) C. Diff was performed on patients on 10/13/2021, 10/18/2021, and 12/20 /2021. 2. A review of Quality Control records revealed the following: a) Serum hCG- No acceptable QC was documented. This was noted for 12 out of 12 months reviewed. d) C. Diff- No acceptable QC was documented. This was noted for 12 out of 12 months reviewed. 3. During an interview on 08/09/2022 at 3:00 PM, Testing Personnel #1 confirmed QC for both Serum hCG and C. Diff were only performed with each new lot number. The surveyor explained both of these tests are moderate complexity, and QC must be performed each day of patient testing unless the laboratory has implemented an IQCP. The Supervisor confirmed there was no documentation of QC from July 2021 to July 2022 and the laboratory had not implemented an IQCP.