Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301897	06/17/2026
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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: D5429 Based on review of maintenance records for the Hematology instrument Beckman Coulter DxH 520, and an interview with the Technical Consultant (TC), the laboratory failed to document monthly maintenance as per the manufacturer's requirements. This was noted for 3 out of 12 months in 2025. The findings include: 1. A review of maintenance records for the Beckman Coulter DxH 520 revealed no evidence of monthly maintenance documentation for the following months in 2025: a. July, October, and November. 2. A further review of the DxH 520 Maintenance Checklist revealed, "Monthly ... Perform Bleach cycle and clean the white blood cell bath filter." 3. During an interview on 6/17/26 at 2:02 PM, the TC noted that monthly maintenance was not documented.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

	This STANDARD is not met as evidenced by: D5441 Based on a review of Vitros XT 3400 Chemistry analyzer Quality Control (QC) records and an interview with the Technical Consultant, the laboratory failed to have a procedure in place that monitors the accuracy and precision of test performance over time. This was noted from the date of the previous survey 5/30/24 to the date of the current survey 6/17/26. The findings include: 1. A review of Vitros XT 3400 Chemistry QC records revealed no evidence of correct Levy Jennings charts or peer group data available for review during the time of survey. 2. A further review revealed Levy Jenning charts but inaccurate ranges per manufacturer requirements. 3. During an interview on 6/17/26 at 2:02 PM, the Surveyor inquired about the review of Levy Jennings charts for the Vitros XT 3400 Chemistry analyzer. The TC confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: D5445 Based on a review of the Ortho Quidel Triage QC (Quality Control) records, the QuickChek Clostridium Difficile (C. diff) QC records, the serum hCG (Human Chorionic Gonadotropin) QC records, the IQCP (Individualized Quality Control Plan), and an interview with the Technical Consultant (TC), the Laboratory failed to ensure Testing Personnel (TP) performed the Triage, C.Diff, and serum hCG QC every 30 days as per the IQCP. The surveyor noted the following QC was not performed as required by the IQCP: a) Triage QC 41 days of 17 months reviewed in 2025-2026, b) C. diff QC February 2025, c) Serum hCG QC February 2025. The findings include: 1. A review of the Ortho Quidel Triage QC records, QuickChek C. diff QC records, and serum hCG QC records revealed the following QC not performed every 30 days or monthly per IQCP: a) Triage Cardiac QC performed 2/15 /25 and then 38 days later on 3/31/25; also Cardiac and Ddimer performed 2/1/26 and then 29 days later on 3/31/26, b) C.diff QC performed 1/15/25 and then not again until 3/15/25, c) Serum hCG QC performed 1/15/25 and then not again until 3/15/25. 2. A review of the Triage IQCP revealed, "Perform external Quality Control at least every 30 days." A review of the C.diff and serum hCG IQCP revealed, "Perform QC monthly ..." 3. During an interview on 6/17/26, at 2:02 PM, the TC confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the

	manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: D5481 Based on a review of the 2025 Cardiac quality control (QC) records, and an interview with the Technical Consultant (TC), the laboratory failed to ensure at least two levels of QC were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted 1 day out of 12 months reviewed in 2025. The findings include: 1. A review of the QC records for the Quidel Triage Cardiac analyzer revealed the following dates QC was out prior to patient testing: a) Level 2 out on 2/15/2025. 2. During an interview on 6/17/26 at 2:02 PM, the TC confirmed the above findings.