Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2074713	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Accordia Healthcare, Llc	3193 East First St, Vidalia, 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 January 23, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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: Based on the review of the Horiba 60, Hematology Analyzer Quality Control (QC) documents and staff interfiew the laboratory was releasing Hematology patient results even when the QC was not within acceptable range. Findings: 1. Review of the QC documents for the Horiba 60 hematology analyzer showed that from October 11, 2017 to October 18, 2017, the QC was not acceptable on two out of the three controls. There were 28 Hematology patient samples tested and reported during the aforementioned dates that the control results were not within an acceptale range. For dates December 20, 21, 22, 2017, it appeared the dates were deleated from the monthly QC reports but individual instrument printouts were located and the QC results were not acceptable. There were 17 Hematology patient samples tested and reported during the dates. 2. Interview with staff #7 (CMS form 209) on January 23, 2019 at approximately 3pm in the staff breakroom, confirmed that patients samples were being tested when the QC was not acceptable in October, and December 2017.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Horiba 60 Hematology Analyzer Quality Control (QC) documents, the Laboratory Director (LD) failed to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. Based on review of the Horiba 60 Hematology QC documents, the laboratory failed to assure the quality of the hematology results before allowing patients to be reported. From October 11 thru the 18, 2017, and December 20, 21 and 22, 2017 the Hematology QC was not within an acceptable range, and patient sample were ran and resulted. 2. Interview with staff #7 (CMS 209 form) on January 23, 2019 at approximately 3:30 pm in the staff breakroom, confirmed that the LD failed to assure the quality of laboratory services for the QC, from October 11 thru the 18, and December 20 thru the 22, 2017.