Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2259316	11/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Accordia Urgent Care & Family Practice	1301 Statesboro Place Cir #1582, Statesboro, 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 recertification survey was performed on November 2, 2023. An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties/subspecialties for 42 CFR. NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control(QC) for the Abbott iSTAT and staff interview, the laboratory failed to perform QC on the iSTAT, each day of use of the NON-Waived Blue Cartridge 8+ for Chemistry testing, Chem 8 profile. Findings: 1.

	Review of the QC for the Abbott iSTAT for performing the Chem 8 profile, using the NON-Waived Blue Cartridge 8+. The laboratory was only performing QC on new lot numbers received, monthly QC, and each shipment. 2. Interview with the Lab Manager (LM) on November 2, at approximately 2pm in the front office, confirmed the aforementioned statement.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for 2022-2023 and staff interview, the Laboratory Director (LD) failed to ensure that the QC for the NON-Waived Abbott, iSTAT handheld analyzer for the performance of the Blue Chemistry Cartridge for Chem 8+ testing met the Clinical Laboratory Improvement Act requiring NON-Waived Chemistry testing analyzers have QC performed on each day of use. Findings: 1. A review of the QC for the Abbott iSTAT Chemistry analyzer confirmed the laboratory was only performing QC on new lot numbers of testing cartridges, new shipments, and every 30 days. Chemistry analyzers must be verified by performance each day of testing. 2. Interview with the Laboratory Manager, on November 2, 2023, at approximately 2pm, in the front office, confirmed the aforementioned statement.