Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0902285	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Georgia Skin & Cancer Clinic	900 Mohawk Street, Suite E, Savannah, 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 October 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 deficiencies were cited:
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 review of patient logs and staff interview, the laboratory failed to perform qualitative QC on each day of patient testing as required. Findings include: 1. Review of patient logs revealed Potassium Hydroxide (KOH) and Wet Preparation (Parasitology) QC was not performed for 2018 (February through December) and 2019 thus far. 2. An interview with the office manager in a conference room on 10/23 /2019 at approximately 10:00 a.m. confirmed the lack of the aforementioned QC for 2018 and 2019.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory

	director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/technical supervisor (LD/TS) failed to ensure the competency of all TP as required. Findings include: 1. TP document review revealed Staff #1 (CMS 209) did not have an annual competency performed for Potassium Hydroxide (KOH) and Wet Mount testing in 2018 and 2019 thus far. 2. An interview with the office manager in a conference room on 10/23/2019 confirmed Staff #1 (CMS 209) did not have an annual competency performed for the aforementioned tests in 2018 and 2019 thus far.