Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0902285	01/24/2018
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 January 24, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) policy for performing potassium hydroxide (KOH) preparations for fungus and Oil preparations for scabies (OIL), review of testing logs and staff interview, the laboratory failed to follow its written policy of monthly internal peer review and external quality review every 6 months. Finding include: 1. Review of the laboratory's QA policy revealed monthly internal peer review is required and every 6 months an external review is required. 2. Review of the laboratory's testing logs from February 2016 through January 2018 revealed QA review was performed on 4/26/16, 7/15/16, 1/12/17, 8/22/17 and 11/4 /17. The log does not indicate whether this is internal or external review. No other documentation of QA review is available. 3. Interview with the office manager at 2 pm on January 24, 2018 in the laboratory confirmed no records of monthly internal peer review are available and records do not indicate whether documentation of QA review is internal or external.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290

	Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient tests records (Mohs cards and Mohs notes) and patient test reports as well as telephone and email correspondence with the laboratory director /dermatologist, the laboratory failed to ensure the information documented on the patient tests records and patient reports was correct. Findings include: Refer to D 5801
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient tests records (Mohs cards and Mohs notes) and patient test reports as well as telephone and email correspondence with the laboratory director /dermatologist, the laboratory failed to ensure the information documented on the patient tests records and patient reports was correct. Findings include: 1. Review of 2 of 4 patient test records (Mohs notes/cards) and the corresponding patient reports revealed the patient reports and patient test records did not agree. 2. Review of Mohs case # S18-6439 revealed the Mohs notes documented an additional section was necessary due to incomplete epidermal margin of excision in specimen # 2. No results of the microscopic examination of the additional section are documented on the Mohs card or notes. The patient report states "Microscopic tumor was found persisting in specimen # 2 but due to the incomplete epidermal margin of excision in specimen # 2, an additional section was necessary. The report is marked showing a correction needs to be made to remove "Depth of Invasion, Cell Morphology and Pattern" on stage 1 and all verbiage concerning Stage 2. Email correspondence with the laboratory director/dermatologist on February 9, 2018 at 12 pm revealed additional sections were performed and complete margins were demonstrated, however: his failure to remove the marking on the Mohs card resulted in the wrong box being checked on the Mohs note which incorrectly stated and additional stage was necessary. 3. Review of Mohs case # S18-6439 revealed the Mohs notes show the tumor was divided into 2 sections and the tumor was persisting in specimen # 1.2 and negative but in specimen 1.2, due to inflammation, an addition piece was taken. The patient report states microscopic tumor was found persisting in specimens # 1 and # 2 :negative, but in specimens #1 and # 2, due to inflammation and additional piece was taken. A notation is made to correct the report by removing "an additional piece was taken". Email correspondence

	with the laboratory director/dermatologist on February 9, 2018 at 12 pm revealed the tumor was completely removed, there was residual inflammation and that no additional stages were necessary.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form listing testing personnel, review of laboratory records, lack of records to review and staff interview, the technical consultant failed to perform the required yearly competency assessment on 10 of 10 testing personnel in 2016 and 2017 who evaluate and report results on Fungal potassium hydroxide (KOH) preparations and Oil preparations for scabies (OIL), . Findings include: 1. Review of laboratory records revealed no documentation of competency assessment including the six required components on 10 of 10 testing personnel in 2016 and 2017 . 2. Interview with the office manager on January 24, 2018 at 2 pm in the laboratory confirmed there is no documentation of competency assessment for testing personnel performing KOH and OIL preparations.