Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1007143	10/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Christina G Steil Dermatology, Ltd	125 W 2nd St, Hinsdale, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report - CLIA (FORM CMS 209); laboratory policies and procedures manual; and personnel records; and interview with the practice manager, the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. Findings include: 1. Review of FORM CMS 209 revealed that there were persons listed as follows: a. Personnel #1 was listed as the Laboratory Director who was also listed as one of the Clinical Consultants (CC) b. Personnel #2 was listed as CC; Technical Supervisor (TS); General Supervisor (GS); and High Complexity Testing Personnel (HCTP). c. Personnel #3 was listed as CC, TS, GS, and HCTP. d. Personnel #s 4, 5, 6, 7, and 8 were all listed as HCTP who only process tissue specimens. 2. Review of the laboratory's policies and procedures manual revealed that there was a procedure that described the process for assessing the competency of personnel who process tissue specimens. There were no procedures that described the process for assessing the competency of the technical supervisors; clinical consultants; and testing personnel who read biopsy slides. 3. Review of personnel records revealed that there was no documentation to show that a competency assessment was performed on the following personnel: a. 1 of 2 Technical Supervisors b. 2 of 2 Clinical Consultants c. 1 of 5 personnel who process tissue specimens for Mohs (personnel #4 on FORM CMS 209). 4. At 11:00 AM on October 12, 2018, the practice administrator confirmed the surveyor's findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM CMS 209); personnel records; proficiency testing (PT) records; and interview with the practice administrator, the laboratory failed to verify the accuracy of any test or procedure it performed, at least twice annually. Findings: 1. The laboratory listed a total of 8 testing personnel responsible for high complexity testing in the laboratory. Three out of 8 of these testing personnel read and reported histopathology test results. 2. Review personnel records revealed that there was no documentation to show twice yearly verification of PT performance in histopathology for 2 of 3 personnel performing histopathology. 3. At 11:30 AM on October 12, 2018, the practice manager confirmed the surveyor's findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Base on observations; review of laboratory policies and procedures manuals; patients test records; Laboratory Personnel Report (FORM CMS 209);band interview with the practice administrator, a written procedure manual for all tests, assays, and examinations performed by the laboratory were not available to, and followed by, laboratory personnel. Findings include: 1. On October 12, during the onsite survey, the surveyor performed a look back of testing performed in the laboratory. The look back consisted of the following: a. Review of the laboratory's Mohs testing log where the surveyor selected patients' names for a look back. b. Review of the pathology report c. Review of Quality Control (QC) records d. Review of patients' slides and QC slides to determine retention of slides. The review of patients' slides revealed that there were specimen slides where biopsy slides were filed with Mohs slides. 2. Review of the laboratory's procedures manual revealed that there were only procedures that described Mohs testing. There were no written procedures that described the laboratory's process for testing and reporting results for biopsied tissue specimens. 3. Review of biopsy slides along with their corresponding test reports revealed that there were pathology results reported for 5 of 5 patients' biopsy slides reviewed. 4. Review of FORM CMS 209 revealed that personnel # 3 was the pathologist who interpreted and reported biopsy test results for 5 of 5 patients' biopsy slides reviewed. 5. On October 12, 2018 at 11:30, the practice administrator confirmed the surveyor's findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Base on review of laboratory policies and procedures manual and patients' test reports and interview with the practice administrator, the procedures manual did not include all applicable steps for how it tested biopsy specimens. Findings include: 1. There were no written procedures that described requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493. 1242. 2. There were no written procedures that described microscopic examination, including the detection of inadequately prepared slides. 3. There were no written control procedures. 4. There were no written procedures that described corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. 5. There were no written procedures that described imminently life-threatening test results, or panic or alert values. 6. There were no written procedures that described the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. 7. There were no written procedures that described the course of action to take if a test system becomes inoperable. 8. Review of 5 patients' test reports revealed that the interpretation of biopsy slides were reported on 5 of 5 biopsy slides reviewed. 9. At 11:30 AM on October 12, 2018, the practice administrator confirmed the surveyor's findings
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (FORM CMS 209) and the

	laboratory's procedures manual; and interview with the practice administrator; the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant, and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Findings include: 1. Review of FORM CMS 209 revealed that persons were listed on the form occupying the following laboratory positions: a. Personnel #1 was listed as the Laboratory Director who was also listed as one of the Clinical Consultants (CC) b. Personnel #2 was listed as CC; Technical Supervisor (TS); General Supervisor (GS); and High Complexity Testing Personnel (HCTP). c. Personnel #3 was listed as CC, TS, GS, and HCTP. d. Personnel #s 4, 5, 6, 7, and 8 were all listed as HCTP who only process tissue specimens. 2. Review of the laboratory's policies and procedures manual revealed that there was no documentation to show that the laboratory director assigned personnel #s 3, 4, 5, 6, 7, 8 to their positions in the laboratory, and the duties and responsibilities associated to each position for 6 of 8 laboratory personnel. 3. On October 12, 2018 at 11:30 AM, the practice administrator confirmed the surveyor's findings