Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2076774	08/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southern Skies Dermatology & Surgery	300 Medical Center Drive, Suite 402, Gadsden, AL	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on reviews of the quality control (QC) and maintenance records, the MOHS surgery patient log, and an interview with MOHS Tech #4, the surveyor determined the laboratory failed to retain 2016 QC and maintenance documentation for two years as required by CLIA regulations. The findings include: 1. A review of laboratory records revealed no September thru December 2016 documentation for the following: A) No "Stain Quality / Slide Quality" records B) No maintenance logs for Cryostat #2 or #4 C) No Hematoxin and Eosin (H&E) staining solutions maintenance logs 2. A review of the MOHS surgery patient log revealed 436 MOHS surgical procedures were performed between 9/26/2016 and the end of December 2016. 3. In an interview on 8/23/2018 at 10:45 AM, MOHS Tech #4 was asked for the above missing records; however she was unable to locate them in the on-site documentation. The surveyor explained she could forward the documents to the CLIA office by Monday 8/27/2018 at 9:00 AM. However, no documentation has been received, thus the above noted findings were confirmed. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the laboratory's policies, manufacturers' specifications in the Leica cryostat user's manuals, a lack of temperature logs for the Leica cryostats, and an interview with MOHS Tech #4, the laboratory failed to define appropriate acceptable temperature ranges for the cryostats (as defined by the manufacturers), and failed to monitor and document cryostat temperatures each day of patient testing as per laboratory policy in 2016 thru 2018. The findings include: 1. A review of the laboratory policy entitled, "Cryostat Temperature Checks" specified "Cryostat temperatures are taken each day of surgery...". 2. A review of temperature requirements for specimen types listed in the Cryostat operator's manuals revealed the following: A) Leica CM 1800 manual on page 18, Skin without fat: -15 to -30 degrees C (Celsius); skin with fat: -30 to -60 degrees C B) Leica Cryocut 1800 manual on page 23, Skin without fat: -10 to -15 degrees C; skin with fat: -30 to -60 degrees C 3. A review of temperature logs revealed, the MOHS Technicians record room temperature and humidity each day of MOHS surgery procedures, however there were no temperatures recorded for the two cryostats in use. 4. In an interview on 8/23/2018 at 12:50 PM, when asked if the staff were monitoring and documenting the cryostat temperatures, MOHS Tech #4 stated they checked them, but have not been recording the temperatures. Thus, the above noted findings were confirmed. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the MOHS Quality Assurance (QA) documentation and an interview with MOHS Tech #4, the surveyor determined the laboratory failed to document their QA reviews and the corrective actions taken for discrepant diagnoses in the MOHS surgical slide interpretations by outside pathologists. This was noted in 7 out of 146 cases on 16 MOHS QA logs. The laboratory further failed to document the Laboratory Director's reviews when the documents were returned for 13 out of 16 QA logs. The findings include: 1. A review of laboratory procedures revealed Histopathology slides from frozen section specimens collected during MOHS surgery cases were sent out quarterly for review by pathologists at the Skin Dx Laboratory for diagnosis and accuracy. 2. A review of the QA log revealed the laboratory documented the Case numbers (#), the diagnoses, signature and the date of the Pathologist's interpretations; the Laboratory Director's (LD) signature and diagnosis, and the date the slides were sent. 3. A review of the 2017-2018 QA logs revealed the following discrepant diagnoses: A) Dated sent: 8/03/2017; Case # 17G-0648 1G; Pathologist-Positive; LD-Negative B) Dated sent: 8/16/2018; Case # 18G-0335 1D; Pathologist-Positive-BBC; LD-Negative C) Dated sent: 8/16/2016; Case # 18G-0467 1C; Pathologist-Positive-CIS; LD-Negative D) Dated sent: 8/16/2017; Case # 18G-0513 1C; Pathologist-Negative; LD-Positive E) Dated sent: 8/16/2017; Case # 18G-

	0618 2C; Pathologist-Negative; LD-Positive F) Dated sent: 8/16/2017; Case # 18G-0625 2C; Pathologist-Negative; LD-Positive G) Dated sent: 8/16/2017; Case # 18G-0801 3D; Pathologist-Negative; LD-Positive The laboratory further failed to document the Laboratory Director's reviews (as indicated by his signature and date) of the pathologist's interpretations when the documents were returned for thirteen out of sixteen QA logs. 4. In an interview on 8/23/2018 at 1:00 PM, the surveyor reviewed and confirmed the above noted findings with MOHS Tech #4. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor