Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1016165	05/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chattanooga Skin And Cancer Clinic	6061 Shallowford Road, Chattanooga, TN	

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 observation of the laboratory, review of the laboratory procedure manual, review of the CMS Laboratory Personnel Report (CMS 209 form) and training and competency assessment records for testing personnel, and interview with the lab processing tech, the laboratory failed to establish written policies/procedures to document testing personnel training and competency assessment for performance of Potassium Hydroxide (KOH) in 2022 through survey date of 05.16.2023. The findings include: 1. Observation of the laboratory on May 16, 2023 at approximately 9:00 a.m. revealed a microscope and KOH reagent in use for patient testing. 2. Review of the laboratory procedure manual revealed no policy/procedure for testing personnel training and competency assessment. 3. Review of CMS 209 form and personnel training and competency assessment records revealed no documentation of testing personnel training or competency assessment for 11 of 12 (Testing Persons # 2-12 on CMS 209) testing personnel performing KOH patient testing. 4. Interview with the lab processing tech on May 16, 2023 at approximately 12:45 p.m. confirmed the laboratory failed to establish written policies/procedures to document testing personnel training and competency assessment for performance of KOH patient testing in 2022 through survey date of 05.16.2023 for 11 of 12 testing personnel.
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 observation of the laboratory, review of laboratory records, and an interview with the lab processing tech, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) examination twice per year in 2021 and 2022. The findings include: 1. Observation of the laboratory on May 16, 2023 at approximately 9:00 a.m. revealed a microscope and KOH reagent in use for patient testing. 2. Review of laboratory verification of accuracy records for KOH revealed verification of accuracy was not performed twice a year in 2021 and 2022. 3. Interview with the lab processing tech on May 16, 2023 at approximately 12:45 p.m. confirmed the laboratory failed to verify the accuracy of KOH testing twice a year in 2021 and 2022.
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 observation of the laboratory, review of the manufacturer's instructions for use manual, environmental records request, and interview with the lab processing tech, the laboratory failed to monitor and document room temperature and room humidity in the area where the cryostat was being used for processing tissue removed during MOHS procedures in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on May 16, 2023 at 9:00 a.m. revealed two Leica CM1950 Cryostats (Serial Numbers: 047742467 and 00000005623) in use for processing tissues removed during MOHS procedures. 2. Review of the manufacturer's instructions for use manual revealed the Leica CM1950 environmental specifications are as follows: -operating temperature: 18 degrees Celsius to 35 degrees Celsius -relative humidity (operation): 20% to 60% 3. Request of environmental records revealed no records for monitoring and documenting room temperature and room humidity available for surveyor review. 4. Interview with the lab processing tech on May 16, 2023 at approximately 9:10 a.m. confirmed the laboratory failed to monitor and document room temperature and room humidity for the use of the Leica CM1950 in 2021, 2022, and 2023.