Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2174133	10/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Center For Dermatology, Pllc - Skin Science	2777 E Camelback Rd Ste 140, Phoenix, AZ	

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
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 lack of temperature records from two out of two testing dates in December 2023 and interview with the facility personnel, the laboratory failed to monitor and document the room temperature and humidity of the area where dermatopathology reagents are utilized and stored and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs and Frozen Biopsy testing. Findings include: 1. The laboratory processes specimens and interprets dermatopathology slides in conjunction with Mohs surgery and Frozen Biopsies, with an approximate annual test volume of 250. 2. No documentation of the room temperature was presented for review from 12/01/23 and 12/12/23, to indicate the laboratory monitored and documented the temperature of the room where dermatopathology reagents are utilized and stored each day of testing. 3. No documentation of the ambient humidity measurement was presented for review from 12/01/23 and 12/12/23, to indicate the laboratory monitored and documented the humidity of the room where dermatopathology reagents are utilized and stored each day of testing. 4. No documentation of the cryostat temperature was presented for review from 12/01/23 and 12/12/23, to indicate the laboratory monitored and documented the temperature of the cryostat used on each day of testing. 5. A total of 21 patients were tested by the laboratory on 12/01/23 and 12/12/23. 6. The facility personnel interviewed on 10/29

	/24 at 9:35 AM confirmed that the laboratory failed to monitor and document the humidity, cryostat temperature and the room temperature of the laboratory on 12/01 /23 and 12/12/23.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation from 2023 and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. Patient-specific data and the final test result information for Mohs interpretations and Frozen Biopsy testing is manually transcribed by laboratory personnel into the patient's Electronic Health Record (EHR). 2. The laboratory's Quality Assessment policy states, "Biannually, 5 cases will be reviewed and randomly selected. All frozen sections will be pulled for review. If any issues noted they will be documented, and corrective actions taken as appropriate for the findings." 3. No documentation from 2023 was presented for review to indicate the laboratory followed the policy referenced above to ensure patient test results and patient-specific data were accurately and reliably transcribed into the patient's EHR. 4. The facility personnel interviewed on 10/29/24 at 9:50 AM confirmed the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 5. The laboratory performs approximately 250 tests annually under the subspecialty of Histopathology.