Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2122522	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hamblin Dermatology Pllc	2291 W 16th St, Safford, 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
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 lack of accuracy verification documentation for Mohs testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2023. 2. The facility personnel interviewed on 9/25/24 at 2:15 PM confirmed the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2023. 3. The laboratory's reported annual test volume in the subspecialty of Histopathology is 636.
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 lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory

	systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/25 /2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to, Proficiency Testing and/or accuracy verification policies and procedures. 2. The facility personnel interviewed on 9/25/2024 at 2:20 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
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 humidity records for review from 2022, 2023 and 2024, review of the manufacturer's specifications for the Advantik QS12 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Advantik QS12 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 636. 2. The manufacturer's specifications for the Advantik QS12 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. The laboratory failed to provide documention demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from 2022 through 2024 (through the survey date of 9/25/2024). 4. The facility personnel interviewed on 9/25/2024 at 2:00 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.