

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2140806	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Dermatology Associates, Pc	Street Address, City, State 374 Northside Drive, Suite F, Batesville, IN	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record reviews, and interview, the laboratory failed to monitor and document humidity for one of one cryostat (Leica CM1860 SN1520) for 11 of 11 months (January 2023 to November 2023) and seven (PT#1-PT#6, and PT8) of nine patients reviewed. Findings Included: 1. A tour of the MOHS Microscopic Surgery (MOHS) Laboratory on 11/28/2023 at 12:05 pm, revealed a cryostat used for MOHS testing, Leica CM1860 SN1520. 2. Review of the documents "Temperature Log" from January 2023 to November 2023 indicated there was no documentation for Humidity. 3. Review of the binder "CLIA regulations/manual", approved by Laboratory Director on 12/27/2017, revealed the procedure "Quality Control Policy and Documentation" required temperature checks and documentation, but did not require humidity check and documentation. 4. Review of the "Instruction Manual, Leica CM1850 V2.2 12 /2003" Section 3 page 12 "Technical data" requires that air humidity to be lower than 60 percent. 5. Review of patient's records revealed the following patient had MOHS testing performed when humidity was not monitored: a) PT#1 tested on 11 21/2023 for MOHS. b) PT#2 tested on 10/03/2023 for MOHS. c) PT#3 tested on 8/01/2023 for MOHS. d) PT #4 tested on 4/18/2023 for MOHS. e) PT#5 tested on 2/07/2023 for MOHS. f) PT#6 tested on 7/18/2023 for MOHS. g) PT#8 tested on 7/18/2023 for MOHS. 6. During interview on 11/28/2023 at 12:30 pm, Sp-3 (histology technician)</p>

confirmed that humidity was not monitored or recorded. 7. Annual test volume for MOHS testing is 134.