Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0961890	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates, Pc	931 E 86th St Ste 104, Indianapolis, 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	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, record review and interview, the laboratory failed to monitor and document humidity for one of one cryostat (Leica CM1860 SN00000006707) for 25 of 25 months (August 2021 to August 2023) and eight (PT#1-PT#8) of nine patients reviewed. Findings Included: 1. A tour of the MOHS Microscopic Surgery (MOHS) Laboratory on 8/23/2023 at 10:40 am, revealed a cryostat used for MOHS testing, Leica CM1860 SN00000006707. 2. Review of the documents "Temperature Log" from August 2021 to August 2023 indicated there was a column for Humidity 20%-85%, but this column was blank. 3. Review of the binder "Laboratory Procedure Manual", updated 8/17/2021, revealed the procedure "Analytic Systems, 2. Test Systems" which reads; "Applicable temperatures, humidity, and other environmental factors as applicable will be monitored and documented on each day of testing." 4. Review of the "Instructions for Use " manual "Leica CM1860/CM1860 UV" revision I, under "4.1 Installation site requirements", reads; "The place of installation must meet the following requirements ...Relative humidity, maximum 60% (non-condensing) ... Room temperatures and humidity levels in excess of the recommendations above will affect the cryostat's cooling capacity and the lowest stated temperatures will not be reached." 5. Review of patient's records revealed the following patient had MOHS testing performed when humidity was not monitored: a)

	PT#1 tested on 11/5/2021 for MOHS. b) PT#2 tested on 2/11/2022 for MOHS. c) PT#3 tested on 7/1/2022 for MOHS. d) PT #4 tested on 1/11/2023 for MOHS. e) PT#5 tested on 7/12/2023 for MOHS. f) PT#6 tested on 8/11/2023 for MOHS. g) PT#7 tested on 12/9/2022 for MOHS. h) PT#8 tested on 2/17/2023 for MOHS. 6. During an interview on 8/23/2023 at 1:59 pm, Sp-2 (Office Manager) and SP3 (Medical Assistant) confirmed that humidity was not monitored or recorded for the cryostat from August 2021 to August 2023. 7. Annual test volume for MOHS testing is 323.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure four out of six tissue marking dyes (black expired 6/30/2023, yellow expired 7/31 /2023, red expired 7/31/2023, and orange expired 7/31/2023) were not expired for MOHS Microscopic Surgery (MOHS) testing performed from July 1, 2023, to the date of the survey for two (PT#5-PT#6) of nine patients reviewed. Findings included: 1. During a MOHS laboratory tour on 8/23/2023 at 10:40 am, four Tissue Marking Dyes (black, yellow, red, and orange) were open and ready for use. The dyes had the following expiration dates: (black 6/30/2023, yellow 7/31/2023, red 7/31/2023, orange 7/31/2023). 2. Review of patient's records revealed the following patients had MOHS testing performed when Tissue Marking Dyes were expired: a.) PT#5 tested on 7/12 /2023 for MOHS. b.) PT#6 tested on 7/19/2023 for MOHS. 3. Review of the binder "Laboratory Procedure Manual", updated 8/17/2021, revealed the procedure "Analytic Systems, 3. Environment, Instruments, Reagents, Materials, and Supplies", which read, "Supplies and Reagents: ...Expired reagents will be discarded." 3. During an interview on 8/23/2023 at 10:45 am, SP-3 (Medical Assistant) confirmed the black, yellow, red, and orange tissue marking dyes had expired. 4. Annual test volume for MOHS is 323.