Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0915347	09/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Ltd	101 Chesley Dr Ste 100 Georgetown Bldg, Media, PA	

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 review of Mohs Laboratory temperature logs and interview with testing personnel (TP) #11 and 12, the laboratory failed to define acceptable range conditions that are essential for the operation of 4 of 4 Leica CM 1850 Cryostats from 2017 to the date of survey. Findings include: 1. The Leica CM1850 Cryostat Manual, under the technical Date section states, "Operating temperature range (ambient temperature): 18 degrees Celsius to 35 degrees Celsius. All specifications related to temperatures of the cooling unit are valid only for an ambient temperature of 22 degrees Celsius and a relative humidity of no more than 60%!". Cryochamber temperature range: 0 degrees Celsius to -35 degrees Celsius. 2. On the day of survey, 09/25/2018, review of Mohs Laboratory temperature logs revealed that the laboratory does not define ranges for room temperate, 4 of 4 cryostat chambers and room humidity. 3. TP # 11 and TP #12 confirmed the findings above on 09/25/2018 around 2:30 pm.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on tour of the MOHS laboratory, observation of Tissue Marking Dye bottles, interview with Testing Personnel (TP) #11 and 12, the laboratory failed to label 3 of 3 bottles and 9 of 9 aliquots of Davidson Marking System Dyes with open and expiration dates from 2017 to the date of survey. Findings Include: 1. On the day of survey, 09/25/2018, while on tour of the MOHS laboratory, it was discovered that 3 of 3 bottles of Davidson Marking Systems Dye were without open and expiration dates and 9 of 9 aliquots of Davidson Marking Systems Dyes were observed without idenifcation of dyes and expiration dates. 2. TP #11 and TP#12 confirmed the findings above on 09/25/2018 around 2:45 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on, the review of MOHS laboratory quality assessment procedure and interview with Testing personnel (TP) #11 and #12, the laboratory failed to ensure that quality assessment programs are maintained and documented to assure the quality of the Mohs laboratory from 2017 to the date of survey. Findings: 1. At the time of survey, 09/25/2018, the MOHS laboratory could not provide documentation of quality assessment activities performed form 2017 to the date of survey. 2. Review of the procedure manual revealed, that the quality assessment procedure address personnel competency assessment and not the overall quality of the laboratory. 3. TP # 11 and TP #12 confirmed the findings above on 09/25/2018 around 03:00 pm.