Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0977748	02/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Central Florida	3670 Innovation Dr, Lakeland, FL	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record review of Material Data Safety Sheets, direct observation, and interview with Histology Technician, the laboratory failed to dispose of the 95% Reagent alcohol and the 100% Reagent Alcohol according to manufacturer's instructions for 2 out of 2 years (2016-2018). Findings included: A review of the Material Data Safety Sheet instructions for the 95% Reagent Alcohol and 100 % Reagent Alcohol noted "Prevent product from entering drains" and "Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable." During direct observation on 02/28/18 at 11:00 AM, instructions were found on the 100% Reagent Alcohol label that stated "Contact a licensed professional waste disposal service to dispose of this material." During an interview on 2/28/18 at 11:00 AM, the Histology Technician confirmed that the laboratory was not following manufacturer's instructions for disposing of the 95% Reagent Alcohol and the 100% Reagent Alcohol.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based upon record review and interview with the Office Manager, the laboratory failed to keep the package inserts for the Dermatophyte Medium (DTM) for 2 out of 2 years. (2016-2018) Findings included: Package inserts for the Dermatophyte Medium were not available for review on 02/28/18 to determine the acceptable range for the refrigerator. During interview on 02/28/18 at 12:30 PM, the Office Manager stated the laboratory did not keep the package inserts for reference material.
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 record review and interview with the Histology Technician and the Office Manager, the laboratory failed to indicate temperature and humidity ranges on temperature and humidity logs for the cryostats, and for the refrigerator temperature log for the dermatophyte medium for two out of two years (2016-2018). Findings included: A review of the procedure manual (signed by the Laboratory Director 06/01 /17) included a Daily Routine Maintenance Policy and a Mohs Lab Temperature Policy which did not include the room temperature range and humidity range for the cryostats. A review of the instrument manuals revealed that cryostat #1's manufacturer's instructions stated the recommended room temperature be below 22 degrees Celsius and the room humidity be less than 60 % and the cryostat #2's manufacturer's instructions recommended the room temperature be 15-30 degrees Celsius and room humidity should be less 60%. Package inserts were not available for review for the storage temperature for the dermatophyte medium. During interview on 2/28/2018 at 11:00 AM, the Histology Technician stated they did not know the acceptable range for temperature and humidity but knew to keep the laboratory cool. During an interview on 02/28/18 at 12:00 PM, the Office Manager stated they did not keep the package inserts for the dermatophyte medium.
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 and interview with the Office Manager, the laboratory failed to have potassium hydroxide and mineral oil that was not expired for two out of two years (2016-2018). Findings included: During observation on 02/28/18 at 11:50 AM, the potassium hydroxide had sediment in the bottom of the bottle and the expiration

	date was documented as 02/14/16. Also, the label on the mineral oil label showed an expiration date of 12/14. (Photographic evidence was obtained). During an interview on 02/28/18 at 11:50 AM, the Office Manager confirmed the potassium hydroxide and mineral oil was expired and there was no available reagent with a good expiration date.