Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0310678	12/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates, Pc	2885 Boones Creek Road, Johnson City, TN	

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 MOH'S Cryostat Temperature log for 2019 for 2 of 2 cryostats, with documented required temperature range, and interview with Director of Nursing, it was determined the cryostats' temperatures were documented out of range with no corrective action. The findings include: 1. A review of the MOH's Cryostat Temperature log for 2019 showed temperatures documented as (minus 35 degrees Celsius) with the required temperature range set at (minus 18 to minus 32 degrees Celsius) with no corrective action documented for 2 of 2 cryostats. 2. An interview at approximately 2:00 p.m. on December 17, 2019 with the Director of Nursing confirmed the Cryostats' temperatures were documented out of range for 2019 with no corrective action taken. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: ========== Based on review of 4 of 4 testing personnel competencies performing KOH (Potassium Hydroxide) and Wet Prep analysis and upon interview with the Director of Nursing, it was determined the Technical Consultant failed to ensure documented competency assessments for 2018 and 2019. The findings include: 1. Review of 4 of 4 testing personnel (TP) competencies disclosed no competencies for TP #1 and TP #4 for 2018 and 2019 and for TP #3 for 2018 for performing KOH and Wet Prep analysis. 2. An interview at approximately 2:00 p.m. on December 17, 2019 with the Director of Nursing confirmed there were no testing personnel competencies for TP #1 and TP #4 for 2018 and 2019 and for TP #3 for 2018 for performing KOH and Wet Prep analysis. ==========
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 lack of Quality Assessment (QA) program, lack of director reviews of the H&E (Hematoxylin and Eosin) Stain quality for processing and reading MOH's slides, cryostat temperatures, cryostat maintenance documentation and upon interview with the Director of Nursing, it was determined the Laboratory Director did not have a QA program established for 2018 or 2019 to assure quality and identify failures. The findings include: 1. There was no Quality Assessment program established for assuring quality and identifying failures in the MOH's laboratory for 2018 and 2019. 2. There were no director reviews of the H&E Stain Qualities for processing and reading of MOH's slides, no review of Cryostat Temperatures and Cryostat maintenance for 2018 and 2019. 3. An interview at approximately 2:00 p.m. on December 17, 2019 with the Director of Nursing confirmed there was no QA program in place for director review of H&E slides, cryostat temperatures and cryostat maintenance for the two year period. ==========