Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1057816	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermasurgery Associates	12222 Coit Road, Suite 101, Dallas, TX	

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 and interview with the Lab Manager, the laboratory failed to dispose of alcohol and eosin per the manufacturers instructions for 2 out of 2 years (2016-2018) reviewed. Findings Included: During an interview on 11/08/18 at 4:30 PM the Lab Manager revealed that the alcohol and eosin were disposed of down the sink with water. Review of the bottles of alcohol and eosin it revealed that the two chemicals should be disposed of at an approved waste facility.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager the laboratory failed to retain temperature and humidity records for 1 (August 2018) out of 4 months (December 2016, May 2017, November 2017, and August 2018) reviewed. Findings Included: Review of cryostat temperatures, humidity, and room temperature revealed no documentation of temperatures on August 27, 29, and 30 of 2018. Review of daily quality control and patient accession numbers revealed that 14 patients were tested on

	the 27th, 10 patients were tested on the 29th, and 8 patients were tested on the 30th. During an interview on 11/08/18 at 5:00 PM the Lab Manager confirmed the information was missing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to perform competency evaluations on 2 (#B and #C) out of 2 Clinical Consultants and 2 (#B and #C) out of 3 Testing Personnel reviewed. Findings Included: Review of personnel files revealed that Clinical Consultant #B and #C were the same person as #B and #C Testing Personnel. There was no documentation of competency assessments for being the Clinical Consultant or the Testing Personnel for either #B or #C. During an interview on 11/08/18 at 4:45 PM the Office Manager confirmed that there were no competency evaluations for #B or #C.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director the laboratory failed to verify the accuracy of testing at least twice a year for 1 (2017) out of 2 years (2016-20180 reviewed. Findings Included: Review of peer reviews revealed them performed on 11/06/18, 10/27/16, and 04/11/16. During an interview on 11/08/18 at 5: 00 PM the Laboratory Director confirmed that even though performed, there was no other documentation of peer reviews being performed.