Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2080258	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Professionals Llc	153 East Washington St, North Attleboro, MA	

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
D0000	A CLIA recertification survey was conducted for the Dermatology Professionals, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 a record review and interview with the laboratory director the laboratory failed to retain original patient test records for at least 2 years as evidenced by the following: MOHS Mapping Records: a) The facility scans the MOHS map into the patient's electronic medical record (EMR). b) A review of twelve (12) patient records for MOHS slide exams performed between 7/11/17 and 6/25/18 was performed. c) The review revealed the fact that the MOHS surgical maps in the patient's EMR were in black and white for all twelve (12) patient records reviewed, whereas the original hard copy maps that were scanned were color coded for marking and orientation purposes. d) According to the laboratory director interviewed on 7/24/18 at 9:40 am, the support staff scanned the mapping record for each patient into the computer and discarded the original. As a result, the computer scans, being the only record available, did not replicate the original colored mappings. e) As a result of these findings, the laboratory did not retain the MOHS mapping records, in their original form, for a minimum of 2 years. The laboratory performs 1366 procedures annually. .
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 procedure review and interview, the laboratory failed to have policies and procedures in place to verify the accuracy of KOH, wet preps, Tzanck smears as well as Histopathology skin slide exams twice annually. The laboratory director interviewed on 7/24/18 at 9:58 am confirmed that there was no established written policy and procedure for verifying the above listed procedures twice annually. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the new laboratory director failed to approve, sign, and date all laboratory procedures as evidenced by the following: A review of the laboratory procedure for histopathology skin slide exams and Provider Performed Microscopy Procedures (PPMP) revealed that the laboratory director had not documented a review and approval of the procedure manual. The laboratory director confirmed in an interview on 7/24/18 at 9:55 AM that she had not documented a review and approval of the procedure manual. .