Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0947411	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners -Dr Bryan Townsend	8044 Shoal Creek Boulevard, Austin, 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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
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 review of the reagent log, interview, and presurvey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory for Mohs testing for two of two years reviewed. Findings follow. A. Review of the reagent log from 12/2022 - 11/07/2024 was missing the documentation of the chemicals and stains (Bluing, 100% Reagent Alcohol, Acid Rinse, UltraClear, Neg-50, etc.) other than for Hematoxylin and Eosin. B. Interview with the Office Manager/ Mohs tech on November 7, 2024 at 1415 hours in the breakroom confirmed the findings C. Review of the CMS Form 116 showed an estimated annual volume of 3000 blocks.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.

	This STANDARD is not met as evidenced by: Based on review of patient test reports, slides, interview, and pre-survey paperwork, the laboratory failed to ensure Mohs test reports were available for at least 10 years from the report date for three out of 10 cases from 11/07/2014 to 12/31/2017. Findings follow. A. Random review of 10 Mohs cases from 11/07/2014 to 12/31/2017 showed the test reports and maps were unavailable for review for three cases as listed by date and case number: Date Case # 1. 12/03/2014: 700 2. 01/21/2015: 20 3. 07/21 /2015: 479 B. Interview with the Office Manager/Mohs tech on November 7, 2024 at 1520 hours in the breakroom stated the EMR was replaced and they took away access to the old system (EMD) and they no longer had access to old reports and maps of patients that have not been seen at the clinic since they switched to EMA in May 2017. There was no way of knowing which reports were available without pulling each individual chart. C. Review of the CMS Form 116 showed an estimated annual test volume of 3000 blocks. KEY: EMA = Electronic Medical Access
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and interview, the laboratory failed to ensure quality control for the Hematoxylin and Eosin stain was performed among testing personnel providing a diagnostic interpretation in Mohs testing for 19 out of 24 months from November 2023 - October 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Histopathology Mohs Surgery, revised 01/10 /2024, at 7.4 Staining Procedure in Mohs Lab stated, "For quality assurance purposes, the technician will examine the first slide, control slide, run through the staining process. The technician will mark the control slide with the date of testing. The results will be recorded each day in the quality control log." While it is good laboratory practice for the histotech (or Mohs tech) to review the control slide, it is the responsibility of the testing personnel (Mohs surgeon) to perform the QC and document. B. Review of the Daily Quality Control Log: H&E Stain from 11/01/2022 - 10/31/2024 showed the Mohs tech performed and documented QC from April 2023 - October 2024. C. Interview with the Office Manager/ Mohs tech on November 7, 2024 at 1350 hours in the breakroom stated she would look at the slide and document and give the slides to the Mohs surgeon and was following the procedure. D. Review of the CMS Form 116 showed an estimated annual volume of 3000 blocks.