Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2103160	05/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
United Dermatology Associates Of Flower	4335 Windsor Centre Trl Suite 110, Flower Mound, 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	An announced initial survey conducted 05/12/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
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 review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated histopathology (Mohs) procedures at least twice annually for 1 of 1 testing events in 2022. The findings include: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (Mohs) procedures. 2. Review of the laboratory policy titled "PROFIECIENCY TESTING" revealed: "MOHS MICROGRAPHIC SURGEY SKIN SPECIMENS Proficiency Testing Program in the Mohs Micrographic Cutaneous Oncology, and the Pathology laboratory. This laboratory has instituted an External Quality Control Program. Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it our [sic] for a microscopic examination by a Board Certified Pathologist ... Upon receipt of the pathology report from the Pathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in "Proficiency Testing" located in the quality control manual. In the event the pathology report from the Pathologist does NOT match the in-house diagnosis by the physician, an identical slide will be sent, by the tech or risk manager to another outside laboratory chosen from the list below, for

	microscopic examination. Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." 3. Review of the laboratory's records for 2022 revealed no documentation of twice annual accuracy assessments for histopathology (Mohs) procedures. The surveyor requested documentation of twice annual accuracy assessments for 2022. None was provided. 4. During an interview on 05/12/2023 at 09:03 a.m., the Histotechnician confirmed the above findings.
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 on review of laboratory policies, laboratory maintenance logs, direct observation, and confirmed in interview, the laboratory failed to follow their own written policy for performing annual preventative maintenance (PM) on the Avantik QS12 Cryostat in 2022. The findings include: 1. Review of the laboratory policy titled "CLIA and OSHA Regulations For the Physician's Office Laboratory" revealed: "CLIA Regulations/Manual The CLIA (Policies and Procedures) manual has been written by the Laboratory Director... Quality Control Policies and Documentation The following equipment must be monitored: "Cryostat: Temperature Lubricating Cleaning Defrosting Preventative maintenance/grounding checks" 2. Review of the laboratory policy titled "CRYOSTAT MAINTENANCE" revealed: "5. According to manufacturer's instructions, lab personal [sic] should oil weekly, grease monthly and /or perform necessary maintenance. There is a service contract on the machines for yearly preventative maintenance... 8. Preventative maintenance and grounding checks are done and documented annually." 3. Review of laboratory maintenance logs revealed no documentation of preventative maintenance for the Avantik QS12 Cryostat in 2022. The surveyor requested documentation of preventative maintenance. None was provided. 4. During a tour of the laboratory on 05/12/2023 at 11:38 a.m., the surveyor observed the following PM sticker on the Avantik QS12 Cryostat: AVANTIK BIOGROUP Date: 11/30/17 Due: 11/18 The cryostat had not been serviced by the manufacturer in 5 years and 5 months. 5. During the exit interview on 05/12/2023 at 11:51 a.m., the Histotechnician and Laboratory Director confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policy, quality control (QC) log, patient test records,

	and confirmed in interview, the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for 1 of 9 days in 2022 (July to December). The findings include: 1. Review of the laboratory policy titled "CLIA and OSHA Regulations For the Physician's Office Laboratory" revealed: "Quality Control Policies and Documentation Reagents 1. Reagents will be examined upon arrival for any damage to containers 2. Reagent lot numbers and expiration dates will be recorded 3. The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC log." 2. Review of the laboratory's "QUALITY CONTROL STAINING" log from 2022 (July to December) revealed: "Quality Assurance The first case submitted to the mohs lab which consists of NORMAL tissue will be stained for H&E, documented on the control sheet as QA. This slide will be kept in the file with the case. The Quality control for each stain will be documented. Each stain will have the results documented in the procedure ..." Further review of the quality control log revealed no documentation of intended reactivity for the H&E stain on the following day patients were tested and reported in 2022 (July): 07/08/2022 Mohs Case #'s: S22-001, S22-002, S22-003, S22-004, S22-005 3. During an interview on 05/12/2023 at 10:14 a.m., the Histotechnician confirmed the above findings