Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672772	02/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Associated Dermatologists, Pllc	12700 Park Central Drive Ste B-150, 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
D0000	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 direct observation, review of Tissue Tek Prisma Plus automated slide stainer operator's manual, random review of laboratory environmental records (06/2020 and

	12/2020) and staff interview, the laboratory failed to ensure humidity ranges were within manufacturer's specifications for the Tissue Tek Prisma Plus automated slide stainer for 2 of 2 months. Findings included: 1. During a tour of the laboratory area on 02/08/2020 at 11:46am, a Tissue Tek Prisma Plus automated slide stainer was observed to be in use for tissue specimen slide staining. 2. The Tissue Tek Prisma Plus automated slide stainer operator's manual (Revised 21 July 201, 0008181-01, Rev. A) stated the following: "Operating Environment; Relative Humidity; 30-85% (non-condensing)" 3. A random review of the laboratory's environmental records (06 /2020 and 12/2020) revealed the laboratory defined their relative humidity range as 20% - 80%. This relative humidity range failed to ensure the readings were within the manufacturer's specified relative humidity range of 30% - 85% for the Tissue Tek Prisma Plus. Further review of the laboratory's environmental records revealed the following days when the humidity level was NOT within the manufacturer's specified relative humidity range of 30% - 85%. 12/1/2020- 22% Humidity 12/2/2020- 28% Humidity 12/3/2020- 24% Humidity 12/4/2020- 24% Humidity 12/7/2020- 23% Humidity 12/8/2020- 22% Humidity 12/9/2020- 22% Humidity 12/10/2020- 22% Humidity 4. In an interview on 02/08/2021 at 12:00pm in the conference room, the laboratory representatives, after a review of laboratory records, confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions for the Leica ASP300S tissue processor, review of maintenance records from 2019 and 2020 and confirmed in staff interview, it was revealed the laboratory failed to have documentation of performing all required maintenance for the Leica ACP300S tissue processor. Findings included: 1. During a tour of the laboratory area on 02/08/2020 at 11:46am, two Leica ASP 300S tissue processors (Processor C and Processor D) were observed to be in use for tissue processing. 2. A review of the manufacturer's instructions for the Leica ASP 300S tissue processors (V 1.8 RevH- 11/2016) stated the following: "Replacing the active carbon filter: The life of the active carbon filter will depend on the reagent types used and the frequency of vacuum cycles. The filter should be replaced at least every 3 months ...." 3. Review of the maintenance records from 2019 and 2020 revealed the following dates when the active carbon filter was replaced: a. Processor C 05/07/2019 04/06/2020 Active carbon filter replaced 11 months since the last replacement. 10/28/2020 Active carbon filter replaced 6 months since the last replacement. b. Processor D 07/16/2019 Installed 10/28/2020 Active carbon filter replaced 15 months since the last replacement. The laboratory failed to have documentation of performing required active carbon filter replacement maintenance every 3 months for the Leica ACP300S tissue processor. 4. In an interview on 2/08/2021 at 11:40, the Laboratory Manager and laboratory representatives were asked to provide documentation of quarterly maintenance on the Leica ASP300 S- Vacuum Tissue Processor. No documentation was provided. The manager stated the carbon filter was changed when the processors (C and D) alerted the testing personnel, not quarterly as specified by manufacturer's instructions. This confirmed the above findings.