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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D0980717        | <b>(X3) Date Survey Completed</b><br>11/08/2022 |
| <b>Name of Provider or Supplier</b><br>Arlington Center For Dermatology  | <b>Street Address, City, State</b><br>711 East Lamar Suite 200, Arlington, TX |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency 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 deficiency, 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.  |
| <b>D5429</b>              | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the manufacturer's instructions for the Leica ASP300S automated tissue processor, review of laboratory policy, review of the laboratory's maintenance records from July 2022 to October 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing instrument maintenance as required by the manufacturer for 4 of 4 months. Findings included: 1. Review of the Leica ASP300S automated tissue processor manufacturer's instructions (V1.0 English - 07/2006) revealed the following: "7. Cleaning and Maintenance 7.3 Preventative Maintenance Schedule ...Maintenance Activity Daily: Wipe dry retort and lid after completing retort clean cycle, Clean exterior of instrument with soft cloth and minimal amount of xylene, Check retort filter screen for tissue or wax residue, Inspect and, if necessary, adjust paraffin levels, Inspect reagent container levels, Check fluid level sensors and clean if necessary, Check that the reagent bottles are fully inserted in the connection manifolds ...Maintenance Activity Weekly: Lubricate reagent bottle 'O'</p> |

rings and check for damage, Inspect and, if necessary, clean retort lid seal, Inspect and, if necessary, clean wax bath lid seal, Inspect and, if necessary, clean wax bath strainers, Inspect wax bath air vent and, if necessary, clear ...Maintenance Activity Monthly: Examine activated carbon filter, Inspect electrical connectors at the rear panel of the instrument, Inspect and, if necessary, clean inside reagent bottles, Check that the bottle caps and seals of the reagent bottles are in place and tight ... Maintenance Activity Every 3 months: Lubricate reagent bottle 'O' rings and check for damage by using the remote fill/drain system, Replace carbon filter." 2. Review of the laboratory policy titled, "Fixation and Processing" (signed by the laboratory director on 03/03/2022) revealed the following: "4. Procedure (VIP Tissue Tek Processor) ...5. Routine Maintenance for Processor: A. Check levels of solutions B. Check Paraffin temperature daily C. Change #3 80% Alcohol and #4 95% Alcohol once a week D. Rotate #1 and #2 Buffered Formalin, #5, #6 and #7 Absolute Alcohol, #8, #9, and #10 Xylene, and #11, #12, #13 and #14 Paraffin once a week E. Change purge (cleaning solutions) solutions #15 Xylene, #16 Absolute Alcohol and water once a week F. Flush stations #1, #2, #3, and #4 with warm water to avoid build of salt substances once a week before changing solutions G. Replace charcoal filter every 3 months." The laboratory failed to update its policy when the Leica ASP300S automated tissue processor was put into use. 3. The laboratory maintenance record titled, "ASP 300 Smart Processor Preventative Maintenance Schedule" (July 2022 - October 2022) listed the following: "Reagents Changed Bottle 1: 10% NBF Bottle 2: 10% NBF Bottle 3: 70% ETOH Bottle 4: 95% ETOH Bottle 5: 100% ETOH Bottle 6: 100% ETOH Bottle 7: 100% ETOH Bottle 8: Xylene Bottle 9: Xylene Bottle 10: Xylene Bottle 11: Cleaning Xylene Bottle 12: Cleaning ETOH Bottle 13: Water Empty condensate bottle WAX Wax I changed Wax II changed Wax III changed Wax I cleaned Wax II cleaned Wax III cleaned CARBON FILTER REPLACED Replace Carbon Filter" The laboratory record failed to ensure manufacturer's instructions for required instrument maintenance were performed. 4. In an interview on 11/8/2022 at 11:45am in the facility conference room, Testing Person #2, after review of the records, confirmed the findings. Word Key: NBF = Neutral Buffered Formalin ETOH = Ethanol Alcohol