Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1092736	08/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Frederick Dermatology Associates Llc	45 Thomas Johnson Drive, Suite 209, Frederick, MD	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM), review of laboratory records, and interview with the clinic manager (CM), the laboratory failed to document eye wash station checks in 2024. Findings: 1. The "Chemical Hygiene Plan" stated "Eye irrigation sinks will be checked weekly to be assured that they are working properly. The area of contact with chemicals will require that it be flushed with water for at least 15 minutes." 2. The laboratory's SOPM included a log to document eye wash station checks. The log included spaces to record all eyewash checks for one year on a single sheet of paper. 3. Laboratory records did not include an eye wash station check log for 2024. 4. During the exit survey on 07/24/2024 at 12: 10 PM, the CM confirmed that the eye wash station check log had not been completed for 2024.
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 the standard operating procedure (SOP), observation, and interview with the clinic manager (CM), preventative maintenance was not performed on the automatic stainer annually as stated in the SOP. Findings: 1. The "Quality Assurance" SOP stated "All equipment will have yearly preventative maintenance performed by a qualified technician. All maintenance records will be kept on file." 2. The automatic stainer had a sticker affixed to the front that stated maintenance was last performed on 05/26/2022 and was due in June 2023. 3. There were no records that preventative maintenance had been performed on the automatic stainer since 05/26 /2022. 4. In an email received on 08/01/2024 at 10:11 AM, the CM confirmed that there was no documentation that preventive maintenance was performed on the automatic stainer since 05/26/2022.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP), review of the potassium hydroxide (KOH) reagent log, and interview with the clinic manager (CM), the laboratory failed to document when new KOH reagent lot numbers were put into use. Findings: 1. The KOH SOP stated that "If KOH is noted to be expired, the KOH solution will be immediately discarded and a new bottle of KOH solution will opened and documented in the KOH Reagent Log." 2. The "KOH Reagent Log" had a single entry of lot number 1342 with an expiration date of 12/08/2023. 3. On the counter was a bottle of KOH with lot number 000428 and an expiration date of 04/30/2026. Lot number 000428 was not documented on the "KOH Reagent Log" and there was no documentation of when the reagent was put into use. 4. Four patients were tested after 12/08/2023: two on 02/15/2024, one on 03/13/2024, and one on 04/03/2024. 5. During the exit interview on 07/24/2024 at 12:10 PM, the CM confirmed that the new lot of KOH was not documented on "KOH Reagent Log" and it could not be determined when the lot was put into use.
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 review of the standard operating procedure manual (SOPM), review of maintenance logs, and interview with the clinic manager (CM), the laboratory failed to document that weekly, monthly, semiannual, and annual maintenance activities defined in the SOP were performed on the cryostat in 2023 and 2024. Findings: 1. The laboratory had two "Cryostat Maintenance" SOPs. One stated "According to the manufacturer's instructions, lab personnel should oil weekly, grease monthly and/or perform necessary maintenance." The second stated "Clean the instrument thoroughly every six months (January & July). Vacuum the back vent, then remove the back and

	withdraw any fluid from the drip pan. Once a year (January) remove the microtome and clean it under hot running water." 2. The laboratory's SOPM included a "Daily Routine Maintenance Log". The log included spaces to initial when routine maintenance was performed for one year on a single sheet of paper. 3. The logs for 2023 and 2024 were reviewed. The 2023 log included handwritten notes in the margin stating "PM cryostat oiled performed" with the testing person's initials once each month from January through August 2023. There was no indication that the cryostat was oiled on a weekly basis, was greased on a monthly basis, or was thoroughly cleaned every six months and no indication that the microtome was cleaned once a year. 4. There were no additional notes on the 2024 log documenting that weekly, monthly, semiannual, and annual maintenance activities were performed. 5. During the exit interview on 07/24/2024 at 12:10 PM, the CM confirmed that the "Routine Maintenance Log" for 2023 and 2024 did not document that all weekly, monthly, semiannual, and annual maintenance activities were performed on the cryostat.