Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 20D1078412	**(X3) Date Survey Completed** 08/22/2024
Name of Provider or Supplier Dermatology Associates	**Street Address, City, State** 57 Barra Road, Biddeford, ME	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with Histotech #1 (HT1), the laboratory failed to follow written policies and procedures concerning log documentation, Cryostat temperature, and corrective action in the specialty of Pathology. Findings include: 1. Record review of the laboratory's "Quality Control Policies and Documentation" on 8/22/24 revealed the following: a. "Cryostat:.. Temperature range is -20C to -30C... Corrective action is taken and documented if temperature exceeds range." b. The Crystat temperature 32C 6 days in January 2024, 3 days in February 2024, and 31C 1 day in February 2024. c. 40 patient were tested in January 2024, and 30 patients were tested in February 2024. 2. Record review of the laboratory "Quality Control Policies and Documentation" procedure and Laboratory Log on 8/22/24 revealed: a. "Quality Control Policies and Documentation" "All specimens must be recorded in a laboratory log. The following information must be recorded: Patient Name Requesting Physician Date of Collection Time of Collection Patient I.D. number Date/Time of Laboratory Test Test Performed By Diagnosis b. Laboratory log available fields: Patient Name Case # Date Surgical Site Diagnosis Sections per stage 1-8 Recut Requested 3. Staff interview with HT1 on 8/22/24 at 9:00am confirmed the above findings, and corrective action had not been documented . 4. The laboratory performs 1,000 Pathology tests annually.
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 record review and interview with Histotech #1 (HT1), the laboratory failed to define consistent criteria for accurate test system operation of the Cryostat sectioning machine in the specialty of Pathology. Findings include: 1. Record review of the Cyrostat temperature log on 8/22/24 revealed a required temperature range of "-15C TO -35C" and a note stating, "The Cryostats should be maintained at -21*C to -26*C for best mohs sectioning". 2. Record review of the laboratory's "Quality Control Policies and Documentation" on 8/22/24 revealed the following: a. "Cryostat:.. Temperature range is -20C to -30C... Corrective action is taken and documented if temperature exceeds range." b. The Crystat temperature 32C 6 days in January 2024, 3 days in February 2024, and 31C 1 day in February 2024. c. 40 patient were tested in January 2024 and 30 patients were tested in February 2024. 3. Staff interview with HT1 on 8/22/24 at 9:00am confirmed the above findings. 4. The laboratory performs 1,000 Pathology tests annually.
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 lack of documentation and interview with Histotech #1 (HT1), the laboratory failed to document routine daily and monthly maintenance on microscopes. Findings include: 1. Record review of the laboratory's Microscope maintenance policy on 8/22/24 revealed the following, a. "The microscope should be covered at the close of every day" b. "Take extra care to keep the stage of the microscope clean" c. "Wipe eye pieces and lenses with lens cloth" d. "Change bulbs as needed and have regular service contracts performed" e. "Document daily, monthly care." 2. Interview with HT1 on 8/22/24 at 10:00am revealed that microscope "care" was not documented in 2024. 3. The laboratory performs 1,000 Pathology tests annually.