Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2144831	12/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Carrollton Dermatology & Skin Cancer Associates	410 Dixie Street, Carrollton, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 10, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operators procedure (SOP) review and staff interview, the laboratory failed to follow the SOP as written and approved. Findings include: 1. SOP review reveals the laboratory is not following written procedures for recording the

	Avantik QS12 cryostat temperature. The SOP requires a temperature range of -21*C to -30*C. The temperature log lists the acceptable temperature range as -25*C to -35 *C. 2. An interview with the lab director on 12/10/2024 at 11:20 a.m. confirmed the lack of compliance with the laboratory SOP for the aforementioned procedure.
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 observation and staff interview, the laboratory failed to ensure reagents and solutions are not be used after their expiration (exp.) date as required. Findings include: 1. Observation during the laboratory tour on 12/10/2024 at 10:15 a.m. revealed each bottle of tissue marker dyes on the laboratory counter were expired : (Violet #153552, orange #154415, green #154057, blue #153199- Exp. 07/31/24; Black #153190, red #151000 -exp. 06/30/24; yellow #148630- exp.04/30/24). Observation during the lab tour revealed there were no replacement reagents available at the time of survey. 2. An interview with the laboratory director, in the laboratory, on 12/10/2024, at approximately 11:20 a.m. confirmed the findings above.