Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0918760	06/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	8573 County Road 64, Daphne, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on reviews of the Quality Control (QC) MOHS Micrographic Surgery Peer Review (MSPR) records, the Proficiency Testing (PT) Policy and Procedure (P&P) manual, and an interview with Office Manager (OM), the laboratory failed to document PT accuracy verification, at least bi-annually. The surveyor noted one of the five bi-annual PT events reviewed was missing documentation of the peer review from the pathologist and the final accuracy verification review of the LD in 2024. The findings include: 1. A review of the 2023-2025 QC Mohs MSPR records revealed an incomplete documentation of accuracy verification assessments for 2024 PT 2 event, 3 cases. 2. A review of the "Quality Control for Mohs Micrographic" log sheets revealed the Mohs Tech completed the "Date", "Patient Name", "Mohs Number", and "Site" for three patients biannually. The surveyor noted the Mohs Tech also included the Mohs Surgeon's diagnosis with the "Site" information. The case slides and the sheet are sent to a second MOHS surgeon for "Peer Review". 3. A review of the "Quality Control for Mohs Micrographic" Bi-annual Event 2024 #2 sheet revealed the Peer Reviewer failed to document his assessment of the "Stain Technique"," Adequate Specimen Preparation" and the "Diagnostic Interpretation". The second Mohs surgeon only signed and dated the bottom of the form. There was no evidence of the Laboratory Director's review of the returned results to determine completeness or whether there were discrepancies in the any of the cases. 2. A review of the PT P&P for Mohs Micrographic Surgery cases revealed the following instructions were not followed by the laboratory based on the incomplete documentation of assessments and final review. ..."Three cases will be sent internally or externally to another Mohs surgeon to be evaluated for any inconsistencies in the quality and interpretation." ..."

	Upon receipt of the pathology report from the Pathologist/Mohs surgeon diagnosis of the slide specimen will be match to the in-house diagnosis by the physician." 3. During the exit conference on 6-25-2025 at 5:30 PM, the OM confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 a review of the Room Temperature (RT) and Humidity logs, the laboratory analyzers' user manuals and an interview with the Office Manager (OM), the staff failed to document the RT and Humidity for four of the four days of patient testing in October 2023. The findings include: 1) A review of the RT and Humidity logs revealed the staff failed to monitor and document the RT and Humidity of the laboratory when patient testing was performed in October 2023 for the following days 12, 13, 19, and 20. 2) The Thermo Scientific Stainer, Avantik and Leica Cryostat user manuals revealed the following manufacturers' requirement. A) Themo Scientific Linistat Linear Stainer, "Temperature: The operating limits for the Linistat are +5C to +40C (+41F to +104F)". "Relative Humidity: The maximum relative humidity allowed is 80% RH up to 31C, decreasing linearly to 50% RH at 40C." B) Avantik Cryostat QS 11 "recommended an operating condition include room RT range of +5C to +35C (41F to 95F) and a maximum relative humidity of 60%." C) Leica Cryostat, "Operating range: Leica cryostats generally have an operating ambient temperature range of 18C to 35C, though some models like the CM1510 may have a range of 18C to 40C." Maximum relative humidity, the maximum recommended relative humidity for operation is generally 60%, non-condensing. 3) During the exit conference on 06-25-2025 at 5:30 PM, the OM confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 direct observations, reviews of the Quality Control (QC) MOHS Tissue Staining Procedure logs, the patient Provider Performed Microscopy (PPM) logs and an interview with Office Manager (OM) and the MOHS Technician, the laboratory utilized three reagents after expiry for patient testing from the date of the last survey on 12-22-2022 through the current survey on 06-25-2025. The findings include: 1. During the laboratory tour with the OM, at approximately 1:44 PM, the surveyor

	observed Potassium Hydroxide (KOH) reagent, Lot 1033 with an Expiration date of 02-02-2023. No open date was written on the bottle. The expired reagent was used for 16 patient PPM examinations from 02-23-2023 through 12-17-2024. The OM confirmed during the tour, the laboratory did not have any unexpired KOH solution on site. 2. Reviews of the QC Mohs Tissue Staining Procedure logs and patient logs revealed the following reagents were used for patient testing after expiration: A) Hematoxylin Lot 2230833 expired 11-10-2024 and was utilized for nine days after expiration. 135 patient specimens were stained using the expired reagent. B) Bluing Agent Lot 163928 expired 03-31-2023 and was utilized for 22 days after expiration. 242 patient specimens were stained using the expired reagent. C) Xylene Substitute Lot 1278321 expired 05-31-2023 and was utilized for 45 days after expiration. 495 patient specimens were stained using the expired reagent. 3. During the exit conference on 06-25-2025 at 5:30 PM, OM and the Mohs Technician confirmed the above findings.