Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2007295	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, S C Dba Lakeshore	650 3 Mile Road Nw Suite 100, Walker, MI	

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 record review and interview with the Regional Director, Clinical Supervisor Team Lead, and Pathology Personnel, the laboratory failed to perform verification of accuracy testing at least twice annually for its histopathology testing in 2023. Findings include: 1. A review of the laboratory's "Frozen Section Biopsies & Mohs Micrographic Surgery Slides" policy revealed a section stating, "Three cases Mohs surgery will be send internally or externally to another Mohs surgeon to be evaluated for any inconsistencies in the quality and interpretation." 2. A review of the laboratory's verification of accuracy records revealed a lack of documentation for its histopathology testing in 2023. 3. An interview on 5/8/24 at 12:50 pm with the Regional Director, Clinical Supervisor Lead, and Pathology Personnel confirmed the laboratory did not have documentation of twice annual verification of accuracy testing for histopathology in 2023.
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 the Clinical Supervisor Team Lead, the laboratory failed to document room temperature and humidity readings for 6 (2/12/24, 2/26/24, 3/25/24, 4/8/24, 4/22/24, and 5/6/24) of 6 patient testing dates reviewed in 2024. Findings include: 1. A review of the laboratory's "Laboratory Daily Maintenance MOHS" policy revealed a section stating, "Temperature charts and logs are checked daily or whenever in use. Record on appropriate form." 2. A review of the laboratory's "Room Temp/Humidity" log revealed a lack of temperature and humidity readings for the following patient testing dates: a. 2/12/24 b. 2/26/24 c. 3/25/24 d. 4/8 /24 e. 4/22/24 f. 5/6/24 3. An interview on 5/8/24 at 12:43 pm with the Clinical Supervisor Team Lead confirmed the room temperature and humidity readings for the patient testing dates listed above were not available.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinical Supervisor Team Lead, the laboratory failed to perform and document maintenance for its cryostat and automated staining system for 4 (3/25/24, 4/8/24, 4/22/24, and 5/6/24) of 4 histopathology testing dates reviewed in 2024. Findings include: 1. A review of the laboratory's "Stain Maintenance Auto-Stainer" procedure revealed a section stating, "Once per month, or more frequently if needed, the stains/solutions will be emptied and the staining jars will be removed and cleaned with 10% bleach solution. Rinse with distilled water and allow to dry thoroughly. The outer covers can be cleaned with a clean, damp cloth and 10% bleach solution." 2. A review of the laboratory's "Laboratory Daily Maintenace Mohs" policy revealed a section stating, "The cryostat will be wiped out with dry gauze, and then everything will be wiped down with gauze of isopropyl alcohol. After wiping with alcohol, the machine will be dried with a gauze and as soon as the machine goes into defrost cycle will be ready for use." 3. A review of the laboratory's "Automated Stainer Cleaning Log" revealed a lack of documentation of stainer cleaning performed for the following months when histopathology testing was performed: a. March 2024. Patient testing performed on 3/25/24. b. April 2024. Patient testing performed on 4/8/24 and 4/22/24. c. May 2024. Patient testing performed on 5/6/24. 4. A review of the laboratory's "Cryostat Maintenance and Temperature Log" revealed a lack of daily maintenance documentation for histopathology testing dates listed below: a. 3/25/24 b. 4/8/24 c. 4/22/24 d. 5/6/24 5. An interview on 5/8/24 at 12:43 pm with the Clinical Supervisor Team Lead confirmed the documentation of cryostat and automated staining system maintenance was not available.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure staff performing Technical Consultant duties were qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure staff performing Technical Consultant duties were qualified as Technical Consultants for 1 (Technical Consultant #2) of 2 personnel performing testing personnel competency assessments. Findings include: 1. A review of the laboratory's testing personnel competency records for its Potassium Hydroxide and Scabies preparations

	revealed Technical Consultant #2 had performed Testing Personnel #1's competency assessment on 2/22/24. 2. The surveyor requested documentation of qualifications for Technical Consultant #2 showing they had met the Technical Consultant requirements on 5/8/24 at 11:52 am and it was not made available. 3. The laboratory was given an additional 7 days to provide the missing documentation and it was not provided.