Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2032824	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	1300 S Green Bay Rd, Ste 100, Racine, WI	

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
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 surveyor review of procedures and interview with the regional manager, the laboratory procedure did not include step by step timing instructions for fifteen of fifteen staining, rinsing, or fixing steps in the H & E (Hematoxylin and Eosin) staining procedure. Findings include: 1. Review of the procedure manual showed the 'Hematoxylin and Eosin Staining', Policy M721-A-v, included a table with three columns (station, time, and solution) with instructions to complete the table with the steps used for H&E staining specific to this laboratory. The table showed fifteen stain, rinse, or fixation steps in addition to a step to apply a coverslip. The form showed no

	timing requirement for any of the identified steps in the process. 2. Interview with the regional manager (staff A) on July 28, 2023, at 1:30 PM confirmed the laboratory had not documented the timing requirements for the H&E staining process and had not included step-by-step instructions in their procedure.
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 surveyor review of laboratory procedures, manufacturer's instructions, and records and observation of laboratory equipment and interview with the regional manager, staff did not complete the daily cryostat maintenance as required for two of two cryostats. Findings include: 1. Review of the procedure, 'Laboratory Daily Maintenance Mohs' showed the procedure directed, "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 a defrost cycle will be ready for use." 2. Review of the manufacturer's instructions for the Leica CM1850 Cryostat showed the manufacturer directed, "Remove frozen section waste from the cryostat with a cold brush every day." 3. Review of the 'Cryostat Maintenance & Temperature Logs' for the two cryostats showed staff documented completion of required maintenance on July 27, 2023, for both cryostats. 4. Observation of the two cryostats in the laboratory, one Leica CM 1850 and one Advantik QS12, on July 28, 2023, at 1:30 PM revealed the cutting compartment of both cryostats contained frozen section waste from previous cuttings and did not show staff had cleaned the instruments after the last use. 5. Interview with the regional manager (staff A) on July 28, 2023, at 1:35 PM confirmed both cryostats included frozen section waste and confirmed staff had not performed the maintenance on July 27, 2023, as required.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competence assessment records and interview with the regional clinic manager, the laboratory director, who is also the technical consultant, did not document the evaluation of competence for one of one testing personnel who performed moderate complexity microscopy testing in 2022. Findings include: 1. Review of the 2022 competence assessment forms (Log 738-B) revealed a form created January 21, 2023, for staff B. The form showed no evidence the laboratory director, who is also the technical consultant, evaluated the competence of staff B in performing moderate complexity microscopy. The form included three spaces for signatures: the reviewer, technical consultant, and laboratory director. The form showed the director's name hand-printed on the form identifying the director as the

	reviewer, but the director did not sign the form. A second form (M-738-C) 'Bi-annual verification of Ectoparasite specimens' from January 11, 2022, showed testing performed by staff B. This form showed the same patient identification number as the Log 738-B above. The form showed staff B performed a Scabies preparation with a negative diagnostic interpretation. The form showed no evidence of review by a second provider and no evaluation of the accuracy of the results. The form included a space for a verifying physician to sign but showed no signature. 2. Interview with the regional clinic manager (staff A) on July 28, 2023, at 1:30 PM, confirmed staff B was the only testing personnel who performed moderate complexity microscopy in 2022. Further interview confirmed the forms were not complete and confirmed the laboratory director, who is also the technical consultant, did not document evaluation of competence of staff B in 2022 for performing moderate complexity microscopy.