Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1014883	01/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, S C Dba Lakeshore	6225 Prairie Street, Norton Shores, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with the Clinical Manager (CM), the laboratory failed to label the Delasco 20% potassium hydroxide (KOH) reagent with the date the reagent was put into use for 2 (January 2020 to January 2022) of 2 years in possible use. Findings include: 1. During a tour of the laboratory on 1/31/2022 at 9:19 am the surveyor observed the 20% KOH reagent in use did not have an open date and the expiration date is in the future (12/31/2023). 2. When queried on 1/31/2022 at 9:31 am the CM was unable to give a date the reagent had been put into use for testing. 3. An interview on 1/31/2022 at 9:31 am, the CM confirmed there was no open date recorded on the bottle of 20% KOH in use.
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 observation and interview with the Clinical Manager (CM), the laboratory

	failed to perform and document thermometer calibrations for 1 (Serial number (S/N) 181278936) of 1 thermometers in the histopathology laboratory before the expiration date. Findings include: 1. During a tour of the laboratory on 1/31/2022 at 9:19 am, the surveyor observed a ThermoScientific thermometer in use with an expiration date of 5 /15/2020 in the histopathology laboratory for the room temperature and humidity. 2. When queried on 1/31/2022 at 9:30 am, the CM was unaware the thermometer had an expiration date recorded on the back side of the thermometer and that it had expired. 2. An interview on 1/31/2022 at 9:30 am, the CM confirmed the laboratory failed to perform and document thermometer calibration for the expired thermometer or replace it.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Clinical Manager (CM), the laboratory failed to perform and document the cleaning for the mycology and parasitology microscope each day of patient testing for 183 (1/23/2020 to 1/27/2022) of 191 days of testing in 2 years. Findings include: 1. A record review of the "Microscope Maintenance and cleaning (started 10-6-15)" for the Olympus CX31 in nurse station states): a. "The microscope is to be cleaned at least one per day, when the office is seeing medical patients. i. This can be logged either in the KOH or Scabies logs if done directly after a patient. ii. Or done by the nurses and logged on the end of the day checklist. ii. This only needs to be done if the microscope is used". 2. Review of the KOH and Scabies logs revealed for 183 (1/23/2020 to 1/27/2022) of 191 days the maintenance for the microscope cleaning was not marked and the nurse end of the day checklist was either not marked, the days of the weeks not recorded on the logs. 3. An interview on 1/31/2022 at 10:49 am, the CM confirmed the methods of recording the microscope cleaning were not consistently documented and many days were missed
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinical Manager (CM), the laboratory failed to maintain a record system that included the specimen receipt time into the laboratory for each stage of the Mohs' tissue specimen for 3 (NS20-052, NS20-176, and NS20-231) o 14 Mohs' patient charts audited. Findings include: 1.

	Record review for 3 of 14 Mohs' cases reviewed, the laboratory failed to include the specimen receipt time into the laboratory for each stage of the Mohs' tissue specimen recorded on the final Mohs' map as follows: a. NS20-052 - I stage b. NS20-176 - I stage c. NS20-231 - II stages 2. During the interview on 1/31/2022 at 12:07 pm, the CM confirmed the stamping in of the tissue specimens was not present on the final Mohs' maps. ***Repeat Deficiency from the 11/13/2019 survey ***