Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2015844	08/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	1245 Cheyenne Ave Ste 301, Grafton, 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
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 surveyor review of laboratory records and interview with the regional clinic manager the laboratory used expired eosin stain for all Mohs procedures on May 5, 2022. Findings include: 1. Review of the "Quality Control Assessment of Mohs Tissue Staining Procedure" log showed the laboratory used Eosin stain lot 041320 with an expiration date of April 13, 2022 on May 5, 2022. 2. Interview with the regional clinic manager (staff A) on August 23, 2022 at 9:30 AM confirmed personnel used expired eosin stain for all Mohs procedures performed on May 5, 2022.
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 records and procedures and interview with the regional clinic manager, the laboratory staff did not document the performance of daily or monthly cryostat maintenance except on one day during 2021 and on ten of ten days of use in 2022. Findings include: 1. The "Quality Control Policies and Documentation" procedure included the statement, "Interior is cleaned each day after

	use using absolute alcohol, while wearing gloves. The surface is decontaminated each day of use using TBQ or equivalent. The microtome is decontaminated every month using TBQ or equivalent." 2. The "Cryostat Maintenance & Temperature Log" included the following statement, "A checkmark in the Maintenance column indicates that maintenance (per cryostat procedure) is done daily when Mohs is performed." Review of the logs from 2021 and 2022 showed laboratory staff only documented maintenance on one day (July 1) in 2021. Laboratory staff did not document the completion of maintenance for ten of the ten days of cryostat use in 2022. The records showed no sign of monthly maintenance performance. 3. Interview with the regional clinic manager (staff A) on August 23, 2022 at 9:30 AM confirmed testing personnel did not document daily or monthly cryostat maintenance during 2021 or 2022.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and interview with the regional clinic manager, the laboratory director did not ensure prompt review of records and did not ensure maintenance of the quality assessment program in 2021 and 2022. Findings include: 1. Review of "Cryostat Maintenance & Temperature Log" records from 2021 and 2022 showed the records included a space for the team lead or laboratory director to sign and date the record to document review. The records from 2021 were all signed and dated on December 28, 2021; the records from 2022 were not signed or dated and showed no sign of review. The reviewer did not make note of the lack of maintenance documentation in 2021. 2. Interview with the regional clinic manager (staff A) confirmed the laboratory director did not ensure the quality assurance program was maintained when the team lead or director did not review the records for 2021 promptly and did not identify the missing daily cryostat maintenance documentation in 2021 and 2022 (see D5429).