

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2074519	(X3) Date Survey Completed 11/09/2022
Name of Provider or Supplier Forefront Dermatology Sc	Street Address, City, State 244 Westwood Blvd, Columbus, IN	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label 12 out of 12 containers in one of one Thermo Scientific Linistat Linear Slide Stainer to identify reagents used in staining for Mohs Micrographic Surgery (MOHS) slides for seven out of seven patients (PT#1-PT#7) reviewed. Findings Included: 1.) During a tour of the MOHS laboratory on 11/9/2022 at 9:30 a.m., revealed a Linistat Linear Slide Stainer with 12 different reagents in containers with no labeling to identify the reagents and no posted labeling to identify the sequencing on staining in the stain line. 2.) Review of "Stain Line Rotation Log" revealed there was no labeling of containers from the Linistat in the log to identify when the reagents were changed. 3.) Review of Patient records revealed the following: a.) PT#1 was tested for MOHS on 1/6/2021. b.) PT#2 was tested for MOHS on 6/22/2021. c.) PT#3 was tested for MOHS on 10/27/2021. d.) PT#4 was tested for MOHS on 1/3/2022. e.) PT#5 was tested for MOHS on 5/2/2022. f.) PT#6 was tested for MOHS on 8/31/2022. g.) PT#7 was tested for MOHS on 11/2/2022. 4.) The annual testing volume for MOHS is 500. 5.) During an interview on 11/9/2022 at 1:46 p.m., Staff person #1(Regional Manager) confirmed the laboratory failed to label the Linistat to identify the 12 reagents in containers</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

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, record review and interview, the laboratory failed to perform maintenance for one of one Linistat Linear Slide Stainer for two out of two years (January 2021-October 2022) and seven out of seven patients (Pt#1-Pt#7) reviewed. Findings Included: 1.) During a tour of the MOHS Laboratory on 11/9/2022 at 10:22 a. m. revealed a revealed a Linistat Linear Slide Stainer in use for MOHS Slide staining. 2.) Review of "Thermo Scientific Linistat Operator Guide", effective date 1/26/22, read, " Internal Cleaning ... Clean the inner surfaces and compartments as required ... Cleaning Staining Jars ...Clean the Staining Jars as required ..." 3.) Review of the Policy & Procedure: "Stain Maintenance Auto-Stainer", signed by laboratory director on 2/2022, stated "1. Staining dishes will be changed as needed, depending on the number of cases and slides ran daily ... 3. A QC worksheet is documented daily on stain quality and any corrections or changes made ... Stain/Chemical/ Time frame to Change Stain/Chemical 100% Reagent alcohol changed each morning, Eosin changed weekly Hematoxylin changed weekly Scotts bluing changed weekly Ultraclear changed weekly" 4.) Review of January 2021-October 2022 "Stain Log" revealed no written documentation of maintenance for the Linistat for from January 2021 to October 2022. 5.) Review of Patient records revealed the following: a.) PT#1 was tested for MOHS on 1/6/2021. b.) PT#2 was tested for MOHS on 6/22/2021. c.) PT#3 was tested for MOHS on 10/27/2021. d.) PT#4 was tested for MOHS on 1/3/2022. e.) PT#5 was tested for MOHS on 5/2/2022. f.) PT#6 was tested for MOHS on 8/31 /2022. g.) PT#7 was tested for MOHS on 11/2/2022. 6.) The annual testing volume for MOHS is 500. 7.) During an interview on 11/9/2022 at 1:46p.m., SP#1 (Regional Manager) confirmed the laboratory failed to perform maintenance for Linistat from January 2021 to October 2022.