

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2087643	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier Forefront Dermatology, S C	Street Address, City, State 8325 S Emerson Ave Ste C1, Indianapolis, 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 11 of 11 containers of slide staining liquids on the Thermo Scientific Linistain slide stainer to identify reagents used in staining MOHS micrographic surgery (MOHS) slides. Findings included: 1. During tour of the MOHS staining area on 10/25/2022 at 10:19 am, revealed a Thermo Scientific Linistain slide stainer sitting on the counter. The Linistain had 11 containers of different solutions. The Linistain had no labeling to identify what the solutions were. A label on the machine read, "Do not discard reagent inside of container." There was no sign posted to identify staining procedure in use. 2. Review of "Policy & Procedure", signed by the laboratory director on 3/22/2022, states "Subject: Hematoxylin and Eosin Stain... Complete this table with the staining process used in the stainer utilized in the Mohs stainer specific to this location." The table was blank. The sections to complete are "Station", "Time" and "Solution". 3. During interview on 10/25/22 at 2:36 PM, the regional clinic manager confirmed the linistain was not labeled to identify reagents. 4. The annual test volume for histopathology is 750.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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 observation, record review and interview, the laboratory failed to remove one of two potassium hydroxide (KOH) bottles expired on 1/20/2016 and in use for mycology (KOH) and parasitology (scabies) testing performed for four of four (PT#8-PT#11) KOH patients reviewed. Findings included: 1. During a tour of the KOH testing room on 10/25/2022 at 10:43 am, revealed two KOH bottles without open dates or in use dates listed on the bottles. One bottle labeled "KOH 10% wDMSO 31ml" had expired (1/20/2016, lot number 1502014). 2. Review of "Quality Control Policies and Documentation", signed by the laboratory director on 3/22/2022, states "M-721-E-v-Laboratory Chemicals... This office will practice the following policies:... 4. All outdates will be disposed of properly." and "M-721-E-iv Reagents... This office will practice the following policies:...4. All outdates will be disposed of properly." 3. Review of patient records indicated the following patients had KOH testing in 2021 and 2022: a) PT#8 tested on 4/21/2021 b) PT#9 tested on 12/7/2021 c) PT#10 tested on 6/2/2022 d) PT#11 tested on 9/22/2022 4. During an interview on 10/25/22 at 2:36 PM, the regional clinic manager confirmed the expired bottle labeled "KOH 10% wDMSO 30 mil" was not removed for the KOH testing room. 5. Annual test volume for mycology and parasitology is 100.