

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2120567	<b>(X3) Date Survey Completed</b> 01/13/2021
<b>Name of Provider or Supplier</b> Forefront Dermatology, Sc	<b>Street Address, City, State</b> 278 Westlake Road, Hardy, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification on-site survey was conducted at Forefront Dermatology, Sc on January 13, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory was conducted on December 11, 2020 with virtual record review of documentation on January 11, 2021. Specific deficiencies cited are as follows:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedures (P&amp;P), verification of test accuracy records, lack of documentation and interview, the laboratory failed to perform two (2) of 2 verification of test accuracy evaluations for the MOHS micrographic skin specimen testing in the calendar year 2019. Findings include: 1. Review of the laboratory's P&amp;P revealed the following policy, "Verification of Test Accuracy - This laboratory verifies the overall accuracy of Mohs testing by sending at least 2 cases every 6 months to an independent Mohs Surgeon or Dermatopathologist for review. The slides and a copy of the map are sent along with a form for documentation of the review. The review document is filed in a Quality Assurance manual." 2. Review of the verification of test accuracy evaluations from August 22, 2018 to the date of survey revealed a lack of documentation of the verification of test accuracy evaluations as defined by the policy for the calendar year 2019. Documentation of the evaluations were not available for review upon request by the inspector. 3. An interview with the practice manager, histotechnologist and lab director on January 13, 2021 at approximately 11:20 AM confirmed the findings.</p>

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure (P&P) manual, lack of documentation and interviews, the laboratory director failed to review, approve, and sign the new P&P on 8/11/20. Findings include: 1. Review of the laboratory's P&P and interview with the practice manager and Forefront Dermatology regional manager on January 13, 2021 at approximately 11:00 AM revealed that the site became part of Forefront Dermatology and management of the dermatologic specialty on 8/11/20. New policies and procedures were implemented by Forefront Dermatology, Sc. 2. Review of the new P&P revealed a lack of documentation by the lab director indicating review and approval of the P&P at the date of survey. 3. An interview with the practice manager, histotechnologist and lab director on January 13, 2021 at approximately 11:20 AM confirmed the findings.