

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1095708	<b>(X3) Date Survey Completed</b>  04/15/2024
<b>Name of Provider or Supplier</b>  Forefront Dermatology, Sc	<b>Street Address, City, State</b>  5589 North Croatan Highway, Kitty Hawk, NC	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 review of the laboratory's policies and procedures and review of 2022 and 2023 laboratory records 4/15/24, the laboratory failed to verify the accuracy of the KOH (potassium hydroxide) and scabies preps at least twice a year in 2022 and 2023. Findings: Review of the laboratory's policies and procedures revealed "Contract Agreement for Quality Assurance and Proficiency Testing In ordinance with the Center for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments regulation regarding quality assurance and proficiency testing of non-regulated analyte, not covered under Subpart I, biannual verification is necessary. This biannual verification will be done using the split sample technique using another laboratory that performs the same testing procedures. Semi-annually, (the laboratory), Moderate Testing Personnel will have reviewed two or three cases containing the original slides or photographs from the microscope for KOH and Ectoparasite testing ...". 1. KOH Review of the "KOH Examination and QC" procedure revealed "... Accuracy: 1. Verification of the accuracy of the KOH prep is completed with each Provider Performed in Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collecting and reading each test. 2. Provider shall maintain KOH quality assurance (peer review) done bi-annually. The Proficiency testing will be done bi-annually with CAP, WSLH, ACMS, ASMS or other accredited organization, or split sampling (quiz) done annually." Review of 2022 and 2023 laboratory records revealed: a. The accuracy of KOH was verified only once in 2022. On 7/12/22, two providers read a patient KOH prep and documented their results. There was no documentation of any other activity to verify the accuracy of the KOH testing performed by the laboratory. b. The accuracy of KOH was verified only once</p>

in 2023. In January 2023, all providers participated in a "quiz" consisting of a review of blind samples, including KOH. There was no documentation of any other activity to verify the accuracy of the KOH testing performed by the laboratory. 2. Scabies Review of the "Ectoparasite/ Wet Mount Examination" procedure revealed "... Accuracy: 1. Verification of the accuracy of the ectoparasite prep is completed with each Provider Performed Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collecting and reading each test. 2. ... Twice yearly, quality assurance via peer review will be completed and maintained in Quality Control Logbook." Review of 2022 and 2023 laboratory records revealed: a. The accuracy of scabies preps was not verified in 2022. There was no documentation of any activity to verify the accuracy of the scabies preps performed by the laboratory. b. The accuracy of scabies preps was verified only once in 2023. In January 2023, all providers participated in a "quiz" consisting of a review of blind samples, including scabies preps. There was no documentation of any other activity to verify the accuracy of the scabies preps performed by the laboratory.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview with the histotechnician 4/15/24, the laboratory's procedure manual had not been updated to reflect the laboratory's current practice for quality control of the H&E (hematoxylin and eosin) stain. Findings: Review of the laboratory's procedure manual revealed H&E quality control instructions in several different places. For example: 1. Review of the "QUALITY CONTROL PROGRAM" procedure revealed "... M-721-E-i MOHS Specimen ... 2. Collect and hold a specimen from current day's procedures for quality control for use the next day. ..." 2. Review of the "Quality Control Policies and Documentation" procedure revealed "... 1. A 'cleared' specimen set aside from a previous day, has been labeled with the date and path # for identification to be used as a Quality Control stain specimen. ..." 3. Review of the "HEMATOXYLIN AND EOSIN STAIN and TOLUIDINE BLUE STAIN" procedure revealed "... Quality Control: The first slide of the day will be submitted to the Mohs surgeon for the completion of the daily quality control and will be performed using a random non-

diagnostic tissue specimen. The slide will be stained for H&E and documented on the control sheet. It was unclear which of the procedures described the laboratory's current practice. During a telephone interview at approximately 3:15 p.m., the histotechnician stated that they use a debulk procedure on the first patient of the day and if the H&E stain from that patient looks good, they go ahead with the Mohs procedure. .