

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2155881	(X3) Date Survey Completed 09/20/2024
Name of Provider or Supplier Forefront Dermatology - New Hampshire, PLLC	Street Address, City, State 1 Hampton Rd, Bldg B, Unit 208, Exeter, NH	
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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to ensure 3 of 5 Mycology test results were reported in 2024. Findings include: 1. Review on 9/20/2024 of 5 patient records from January to September 2024 revealed 3 patient potassium hydroxide preparation tests (KOH tests) were reported as "+/-" on 5/28/2024, 6/10/2024, and 9/3/2024. 2. Review on 9/20/2024 of the lab's procedure titled "KOH examination and QC" revealed on page 1, under "Documentation" paragraph, instruction to report KOH tests as either positive or negative and include the elements seen for positive findings. There is no instruction in the procedure manual to report a KOH test as both positive and negative. 3. Interview on 9/20/2024 at 9:45 a.m. with the Regional Clinic Manager confirmed the above findings. The Regional Clinic Manager revealed the providers entered "+/-" as an inconclusive result due to the providers seeing fungal elements (positive) and fields of view without fungal elements (negative) from the same sample. 4. The lab was not able to provide any literature references at the time of survey to support a sample with fungal elements seen could be reported as anything but a positive result.</p>
D6070	TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, 3 of 3 testing personnel performing microscopy mycology procedures failed to follow the laboratory's (lab) procedure for reporting test results on 3 of 27 potassium hydroxide preparation tests (KOH tests) in 2024. Findings include: 1. Review on 9/20/2024 of patient log for KOH testing in 2024 revealed 3 of 27 patient results were reported as "+/-". Each of the 3 tests were performed by different testing personnel. Review of the corresponding patient test report for these 3 KOH tests confirmed the result was reported as "+/-". 2. Review on 9/20/2024 of the lab's personnel list (CMS-209) revealed 3 providers perform KOH testing. 3. Review on 9/20/2024 of the lab's procedure titled "KOH examination and QC" revealed on page 1, under "Documentation" paragraph, instruction to report KOH tests as either positive or negative and include the elements seen for positive findings. There is no instruction in the procedure manual to report a KOH test as both positive and negative. 4. Interview on 9/20/2024 at 9:45 a.m. with the Regional Clinic Manager confirmed the above findings.