

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D1048558	<b>(X3) Date Survey Completed</b>  10/23/2024
<b>Name of Provider or Supplier</b>  Forefront Dermatology, Sc DbA Arizona	<b>Street Address, City, State</b>  203 S Candy Lane #14a, Cottonwood, AZ	
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>D5821</b>	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports, review of corrective action documentation and interview with the facility personnel, the laboratory failed to issue an amended test report for one out of one patients tested in the sub-specialty of Histopathology. Findings include: 1. The laboratory performs Mohs on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 250. It is the practice of the laboratory to maintain the Mohs test report (operative note) and the Mohs map in the patient's Electronic Medical Record (EMR). 2. The laboratory's corrective action documentation reviewed during the survey revealed the laboratory identified a discrepancy between the test result listed on the Mohs map and the final test report maintained in the EMR for one out of one patients tested, case# CW23M-084 (MR# 6122565). The operative note listed the final test result as, "Stage 3: No residual tumor seen. There were no malignant cells seen in the sections examined." The Mohs map indicated malignant cells were still present in Stage 3, and the physician performing the procedure noted on the Mohs map, "Pt (patient) doesn't want more stages". 3. No documentation was presented for review during the survey to indicate the laboratory issued an amended test report as a result of the diagnosis discrepancy identified for case # CW23M-084. 4. The facility personnel interviewed on 10/23/2024 at 1:55 PM confirmed the laboratory failed to issue an amended test report for the discrepancy identified in the case stated above.</p>

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of Quality Assessment (QA) records and corrective action forms from 2023 and interview with the facility personnel, the laboratory's QA processes failed to include a review of the effectiveness of corrective actions taken to resolve errors found in the postanalytic systems. Findings include: 1. The 2023 Corrective Action Log presented for review during the survey on 10/23/2024 indicated a test result error was identified by laboratory staff for patient# 6122565 for testing performed on 7/27/23. The log stated, "note indicates clear tumor, map shows positive III stage." 2. No evidence was presented for review to indicate laboratory staff documented corrective action or reviewed the Corrective Action Log to ensure corrective action was taken for the error identified on patient #6122565. The corrective action process must include investigation, identification and resolution of the problem, and development of policies that will prevent recurrence of the problem. 3. The laboratory failed to amend the test report for patient# 6122565 once the test result error was identified by laboratory staff. See D5821 for findings. 4. The facility personnel interviewed on 10/23/2024 at 1:50 PM confirmed that the laboratory's QA processes failed to include a review of the effectiveness of the corrective actions taken for the test report error indicated above. 5. The laboratory performs Mohs on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 250.