

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1095337	(X3) Date Survey Completed 01/23/2024
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 111 Wisconsin American Dr, Fond Du Lac, WI	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the frozen section log and reports, observation of slides, and interview with the Regional Clinic Manager, the laboratory did not follow their procedures for documenting and assigning a unique identification number to two of four frozen section slides reviewed. Findings include: 1. Review of the frozen section log for specimens processed in 2023 showed personnel assigned FS23-0002 through FS23-0004 to Patient 1 on October 30, 2023. 2. Observation of slides on January 23, 2024, at 10:50 AM revealed four slides labeled FS23-0002 through FS23-0004; two slides labeled FS23-0002 and one slide each labeled FS23-0003 and FS23-0004. The label of one of the FS23-0002 slides included the name of Patient 1, the second FS23-0002 slide included the name of Patient 2. 3. Review of patient reports showed a frozen section report for Patient 1 on October 30, 2023. The report identified the tissue from location C as FS23-0002. A report for Patient 2 on October 9, 2023, identified the tissue from location A as FS23-0002. 4. Interview with the Regional Clinic Manager (staff A) on January 23, 2024, at 10:55 AM confirmed FS23-0002 for Patient 2 was not assigned in the frozen section log as required by procedure and confirmed the same accession number was used for two different patient tissue samples.</p>
D5805	TEST REPORT

CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of patient reports and interview with the Regional Clinic Manager, two of three frozen section reports for Patient 1 did not include the microscopic description test results. Findings include: 1. Review of the test report for Patient 1 from October 30, 2023, showed the physician obtained three biopsies (location A, B, and C) by shave method and processed the tissue using frozen section methodology. The report showed: Location / Accession number / result included: A / FS23-0003 / report included microscopic description B / FS23-0004 / no microscopic description C / FS23-0002 / no microscopic description 2. Interview with the Regional Clinic Manager (staff A) on January 23, 2024, at 10:45 AM confirmed the physician did not include the frozen section microscopic description on two of three samples from Patient 1 on the patient report.