

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0584696	(X3) Date Survey Completed 12/20/2023
Name of Provider or Supplier Forefront Dermatology - Pacific, Pc	Street Address, City, State 105 W Mission St, Santa Barbara, CA	
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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of Mohs surgery histopathology slides for five (5) randomly chosen patients, the lack of one patient Mohs surgery histopathology slides, and interview with laboratory's manager; the laboratory failed to retain Mohs histopathology slides at least 10 years from the date of examination. No Mohs records and reports for the same patient were able to be retrieved. Findings included: 1. No Mohs histopathology slides and confidential records from the chart for patient JD Mohs surgery on October 27, 2021, as recorded on the Mohs Pro log, could be retrieved on 12/20/2023 (survey date). 2. The laboratory manager affirmed on December 20, 2023, at approximately 3:00 p.m. that the patient Mohs slides and reports were not found. 3. The laboratory reported volume of 318 Mohs surgeries per year was signed and dated by the laboratory director on 12/20/2023.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the laboratory's policies and procedures, lack of documentation, and interview with the laboratory's manager (LM), it was determined that the laboratory failed to perform and document preventive maintenance and calibration of the Cryostat as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's policies and procedures and Mohs logs indicated that annual maintenance and calibration according to manufacturer's requirements be performed on the Cryostat used to process Mohs surgery samples. 2. The LM confirmed on December 20, 2023, at approximately 3:00 p.m. that the laboratory failed to follow policies and procedures for maintenance and calibration of the Cryostat for the years 2021, 2022, and 2023 indicated by the lack of preventive maintenance documentation. 3. According to the annual test volume declared by the laboratory LD the laboratory performs approximately 318 Mohs tests annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's quality control records, five (5) randomly chosen patient records, and interview with the laboratory manager (LM); it was determined that the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer to support control procedures for the Mohs test used in the laboratory. Findings included: 1. The laboratory used Mohs Pro as Mohs surgery sample processing for patients' samples. 2. At the time of the survey on 12/20/2023 at approximately 2:30 p.m. the LM could not retrieve quality control slides and records for patients' samples processed for Mohs on 10/27/2021. 4. Based on the laboratory testing declaration submitted at the time of the survey, the laboratory cultured and reported approximately 318 Mohs surgery testing samples annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's records for policies and procedures, patients' test results records, preventive maintenance and quality control documentation, and interviews with the laboratory's manager on December 20, 2023;

it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3041, D5429, and D5445.