Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0584696	06/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology - Pacific, Pc	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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on random dermatopathology record review and interview with the laboratory staff on June 24, 2021, the laboratory failed to have a document retention policy and follow it to retain documentation at least 2 years from the date of examination. The findings included: 1. On the day of survey, June 14, 2021 at approximately 11:45 a. m.; a random sampling of the laboratory's dermatopathlogy patient logs were reviewed for a patient sample selection of Mohs procedure mapping and record review. 2. For five (5) dermatopatholgy cases selected, the laboratory could not retrieve two (2) patients' Mohs documentation and mapping notes. 3. The laboratory staff confirmed by interview on June 24, 2021 at approximatelyb 12: 15 p.m. that the laboratory did not find the records requested. 4. The laboratory reports performing approximately 830 dermatopathology patient tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, and interview with the practice administrator (PA), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, June 24, 2021 at approximately 11:00 a.m., the surveyor found the following reagents being used beyond its expiration date: Reagent Lot number Expiration date Acetone 5339-00 20/2019 Scoffs Water J080-01 03/23 /2021 KOH 1909814 04/07/2020 2. The PA affirmed on 06/24/2021 at approximately 11:10 a.m. using the reagents listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 830 tests 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 review of the laboratory's records for evaluation of patient reporting, policies and procedures, expiration date of reagents in use, and interview with laboratory staff on June 24, 2021; it was determined that the laboratory director failed to ensure that several aspects of the preanalytical and post analytic phases of laboratory testing were monitored. see D3043 and D5417.