Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0533930	10/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc Dba Arizona	2820 Glassford Hill Rd #107, Prescott Valley, AZ	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: **Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2018. Findings include: 1. No documentation was presented for review during the survey to indicate that the laboratory verified the accuracy of Mohs testing at least twice annually during 2018. 2. The laboratory's established policy states, "At least 2 Mohs cases reviewed each year for every location of practice. At least one case reviewed for each Mohs surgeon at all locations per year." 3. The facility personnel confirmed that the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2018 per established policy. ** This is a repeat deficiency from the previous survey conducted on October 24, 2017.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory manual presented during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1.

	The laboratory's procedure manual presented for review during the survey conducted on October 4, 2019 failed to include the approval, signature and date of the laboratory director. 2. The facility personnel acknowledged that the procedure manual was not signed and dated by the laboratory director at the time of the survey.
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 direct observation of stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs testing, with an approximate annual test volume of 1,500 tests. 2. During the survey conducted on October 4, 2019, direct inspection of the Hematoxylin reagent, lot #7575-00, indicated an expiration date of April 2019. 3. The facility personnel confirmed that the expired reagent indicated above was still in use on the day of the survey. The number of patients tested using the expired reagent could not be determined at the time of the survey.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory maintenance policies, microscope maintenance logs and interview with the facility personnel, the laboratory failed to perform and document the annual microscope maintenance as defined by policy during 2017 and 2018. Findings include: 1.The laboratory's established microscope maintenance policy states, "Ocular Micrometer calibrated yearly" and " Grounding and Cleaning yearly". 2. No documentation was presented for review to indicate the laboratory performed the maintenance as indicated above on the microscope during 2017 and 2018. 3. The facility personnel confirmed that the laboratory failed to perform yearly maintenance on the microscope as indicated in policy.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review Mohs surgery slides, patient test reports, Mohs patient log and interview with the facility personnel, the laboratory failed to indicate the correct Mohs accession number on the test records for Mohs testing for one out of the four Mohs cases reviewed. Findings include: 1. Review of the Mohs patient test log and the Mohs slide for patient M.R. tested on 02/27/2018 indicated the Mohs accession number assigned to the case was PV18M-182. The electronic Mohs operative report and the Mohs map for the same Mohs case indicated the accession number as PV18M-023. 2. Review of the patient slide indicated the slide was originally hand labeled with accession PV18M-023, but the laboratory re-labeled the slide with the accession number PV18M-182. 3. The facility personnel stated that the correct Mohs accession number for this case was PV18M-182 as indicated in the Mohs log and on the patient slide, however the laboratory failed to correct the accession number on the electronic operative note and Mohs map.