Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1048563	02/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc Dba Arizona	830 Ainsworth Dr, Prescott, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs log, review of patient slides and electronic test report and interview with the facility personnel, the laboratory failed to follow established procedures to ensure positive identification of patient's dermatopathology specimens. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of histopathology, with an approximate annual test volume of 3,000. It is the practice of the laboratory to assign a unique case number to each patient specimen. The unique case number is included on the Mohs log, Mohs map, patient slide(s) and the patient's electronic test report. 2. The laboratory's established policy titled, "Quality Assessment Procedures" states that, "All QA records such as logs of test requisitions, test reports, and receipt and QA of reagents and culture media that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate, designated staff member every six months". 3. Review of the Mohs log, Mohs map and patient slides for patient# 86764 for testing performed on 12/04/2017 indicated the Mohs case number as P17M-759, while the electronic test report indicated the case number as P17M-754. 4. No Quality Assessment documentation was presented for review during the survey to indicate the laboratory followed their established procedures by reviewing test reports and identifying errors as indicated above, to ensure positive identification and optimum integrity of each patient's specimen throughout the entire test process. 5. The facility personnel confirmed that

	the Mohs case number was entered incorrectly into the electronic test record for the patient listed above and confirmed that the laboratory failed to follow their established procedures to ensure accurate test reports.
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 review of accuracy verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of dermatopathology testing at least twice annually during 2016 and 2017. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 3,000. 2. On the date of the survey, February 22, 2018, the laboratory presented documentation of accuracy verification for Mohs cases that were performed by the laboratory in 2016 and 2017. The facility personnel stated that the laboratory performed the accuracy verification procedure during each respective year, however the original documenation could not be located. The accuracy verification documentation presented for review during the survey for both years (2016 and 2017) was sent for verification by the laboratory in late 2017 and the results were not returned until January 2018. 3. The facility personnel stated that the accuracy verification for Mohs testing was performed for 2016 and 2017 during each respective year but the original documentation could not be located. **This is a repeat deficiency from the previous survey conducted on 01/21/2016.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policies and interview with the facility personnel, the laboratory failed to perform and document QA activities and the laboratory's QA process failed to include a review of the effectiveness of corrective actions taken to resolve problems. Findings include: 1. The laboratory submitted a Plan of Correction for deficiencies cited during the previous survey conducted on 01/21/2016, indicating that the laboratory would conduct a Quality Assessment Review every 6 months (June/Dec) to include the review of "patient case log, Mohs operative reports/maps, control H & E log, reagent log /expirations, room temp/equipment logs, labels on Coplin jars/stain procedure visible, current and updated amendments in CLIA manual, slides labeled/filed, QC slide review sent to Dermpath Diagnostics, equipment PM service, and all QC records present at time of review". The review form requires the laboratory director's signature and date. 2. No documentation was presented for review during the survey to indicate the laboratory performed and documented the QA review stated above

	during 2016 and 2017. 3. No documentation was presented during the survey to indicate the laboratory performed a review of the effectiveness of corrective actions implemented as a result of deficiencies cited during the previous survey, to ensure that the corrective action taken resolved the problem (see D5217 for findings). 4. The facility personnel confirmed that the laboratory did not perform and document QA activities during 2016 and 2017.
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 microscope maintenance as defined by policy during 2016. Findings include: 1.The laboratory's established microscope maintenance policy states, "stages and oculars cleaned day of use". 2. No documentation was presented for review to indicate the laboratory performed the maintenance as indicated above on the microscope during 2016 from July 20, 2016 through the end of the year. The microscope was used for patient testing on approximately 37 days during that time period. 3. The facility personnel confirmed that the laboratory failed to perform maintenance on the microscope as indicated in policy.