

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1048563	(X3) Date Survey Completed 02/06/2020
Name of Provider or Supplier Forefront Dermatology, Sc DbA Arizona	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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 histopathology testing at least twice annually during 2019. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 2,500. The laboratory began biopsy interpretations in December 2018. 2. No documentation was presented for review during the survey conducted on February 6, 2020 to indicate the laboratory verified the accuracy of biopsy interpretations at least twice annually during 2019. 3. The facility personnel confirmed that the laboratory failed to produce evidence of accuracy verifications for biopsy interpretations that were performed in 2019.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a written procedure for review and interview with the facility personnel, the laboratory failed to have a written procedure for testing performed</p>

under the sub-specialty of histopathology. Findings include: 1. The laboratory performs dermatopathology testing, including Mohs and the interpretation of biopsies, with an approximate annual test volume of 2,500. 2. No documentation was presented for review to indicate the laboratory has a written procedure for biopsy testing. The laboratory began testing for the interpretation of biopsies in December 2018. 3. The facility personnel confirmed that the laboratory did not have an established written procedure for biopsy interpretation.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 2,500. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred on 07/10/2018 and 07/11/2018. Approximately 17 patients were tested on those dates. 3. The facility personnel confirmed that the laboratory evaluated the H & E stain acceptability each day prior to testing patients but failed to document the stain acceptability on the dates indicated above.

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 review of patient test reports and interview with the facility personnel, the laboratory failed to include on the biopsy test report the laboratory address where the testing was performed. Findings include: 1. The laboratory performs patient testing in the subspecialty of histopathology with an approximate annual test volume of 8,884. The laboratory began interpreting biopsies in December 2018. 2. During the survey conducted on February 06, 2020, review of patient test report (AP20200000017) indicated a facility address that is not associated with CLIA# 03D1048563. The address listed on the biopsy test report was 18325 N. Allied Way, Phoenix, AZ 85054. The address listed in the CMS CLIA database at the time of the survey for CLIA#

03D1048563 was 830 Ainsworth Dr., Prescott, AZ 86301. 3. The facility personnel confirmed that the laboratory address was not correct on the test report referenced above.