

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1048558	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Forefront Dermatology, Sc DbA Arizona	Street Address, City, State 203 S Candy Lane #14a, Cottonwood, 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 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 documentation 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.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(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</p>

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 for 2016 and 2017 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/expiration, 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 Dermopath 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.