Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1048558	02/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc Dba Arizona	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	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 facility personnel confirmed that the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2018. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 500. **This is a repeat deficiency from the previous survey conducted on 02/22/2018 and 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'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 under 493.1236(c)(1) during the previous survey conducted on 02/22/2018, indicating that the laboratory would conduct a Quarterly QA Review stating, "Every 3 months the Lab Director will pick 2 random cases performed by operating physicians and have Lab Coordinator send the slides to Dermpath Diagnostics or Arizona Dermatopathology for Quality Assurance, Accuracy, and Quality Control. The Lab Director will review the reports from Dermpath Diagnostics or Arizona Dermatopathology. The Lab Director will sign and date that this slide QC has been done, sent and completed. Lab Director signature will attest that all documentation is present and in designated area in the Mohs lab". 2. No documentation was presented for review during the survey to indicate the laboratory performed and documented the quarterly QA review stated above during 2018. 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 under 493.1236(c)(1) 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 indicated above during 2018.
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 500. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred on 01/04/2019 and 01/14/2019. Approximately 25 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.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on repeat deficient practices identified during the survey, the laboratory director failed to ensure that a quality assessment program is maintained to assure the

	quality of laboratory services provided and to identify failures in quality as they occur. See D5217 for findings.