Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1009033	(X3) Date Survey Completed 10/15/2018
Name of Provider or Supplier Advanced Dermatology, A Forefront Dermatology Prac	**Street Address, City, State** 275 Parkway Dr, Lincolnshire, IL	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manual and an interview with the office staff; the laboratory failed to establish policies and provisions to ensure that all records, slides, blocks and tissue are retained and available for the time frames specified in this section for Histopathology. Findings: 1. Review of the laboratory's manual revealed the following: a). The manual does not include how long Histopathology records, slides, blocks and tissue are to be retained; b). The manual does not include established protocols to ensure prompt return of slides, when necessary; and c). If the laboratory ceases operation, what provisions will be made to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section. 2. On an Initial survey conducted on 10/15/2018 at 12:30 PM, the office staff confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's manual, records, and an interview with the office staff; the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Histopathology testing, affecting 2 out of 2 testing personnel (TP). Findings: 1. The laboratory contracts with a mobile testing service which provides equipment and temporary TP for the laboratory to perform Mohs procedures and slide production. The CMS 209 lists 2 temporary TP (TP-2U; listed on line 2 and TP-HH8; listed on line 3) that performs the grossing and tissue staining in the laboratory. 2. The personnel documents provided included competency assessments from the mobile testing service. These assessments were not signed by the technical supervisor (TS) listed on line 1 of the CMS 209. No other documentation was presented as evidence that the competencies of the 2 temporary TP, had not been assessed on-site by the TS, prior to processing patients' tissues from Mohs surgery. 3. Review of the laboratory's manual revealed that it does not include an established competency policy or a step-by-step procedure to assessing TP performing grossing and tissue staining for the production of Histopathology slides. 4. On an Initial survey conducted on 10/15/2018 at 12:30 PM, the office staff confirmed the above findings.
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), laboratory's manual, records, and an interview with the office staff; the laboratory failed to verify the accuracy of tests performed in the specialty of Histopathology at least twice annually for year of 2018. Findings: 1. The CMS 209 list 1 laboratory personnel (TP-VB3; listed on lines 1) performing the slide interpretations for the Mohs surgery procedures. 2. The manual does not include an established protocol or describe a defined method that the laboratory will use to verify the accuracy of it's Mohs procedure and tissue processing. 3. On an Initial survey conducted on 10/15 /2018 at 12:30 PM, the office staff confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's procedures manual and an interview with the office staff; the laboratory's procedures manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory in the specialty of Histopathology. Findings: 1. Review of the manual for Mohs testing revealed that the procedure does not include the following requirements: a). Requirements for the Mohs mobile service, patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. b). Control procedures. c). Imminently life-threatening test results, or panic or alert values. d). The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; and e). Description of the course of action to take if a test system becomes inoperable. 2. On an Initial survey conducted on 10/15/2018 at 12:30 PM, the office staff confirmed the above findings.