Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0975716	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Surgery Associates Llp	815 Hutchinson River Pkwy #793, Bronx, NY	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a lack of procedures, surveyor observation and an interview with the technical consultant, the laboratory failed to establish and have accessible a safety procedure to protect the laboratory staff from physical, chemical, biochemical, biohazard material and electrical hazards. Findings Include: It was confirmed with technical consultants on January 30, 2018 at approximately 11:15 am that two medical assistants were eating and drinking in the laboratory where KOH slides are prepared and read.
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 this surveyor review of the proficiency test verification records and an interview with the technican consultant, the laboratory failed to verify the accuracy of the KOH procedure. Findings Include: On January 30, 2018 at approximately 11:10 AM and confirmed by the technical consultant, the laboratory failed to perform twice

	annual verification for the KOH procedure performed from January 26, 2016 through December 31, 2016. Approximately 344 patient specimens were tested and reported for the KOH procedure performed.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on this surveyors review of the laboratory procedure manual, patient records and an interview with the technical consultant, the laboratory failed to have a written or electronic request for the KOH procedure performed by the physicians.
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 a review of the laboratory procedure manual and an interview with the Moh's processor, the laboratory failed to have a complete procedure manual for histopathology. Findings Include: On January 30, 2018, at approximately 11:00 AM, it was confirmed by the Moh's processor that the laboratory failed to have procedures for the following: 1) Leica Cryostat in use, 2) the labeling of the stain dishes in use, 3) personnel evaluation and time period.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on surveyor's observation, review of the laboratory procedure manual for staining and an interview with the Moh's processor, the laboratory failed to label their staining jars. Finding Include: It was confirmed with the Moh's processor on January 30, 2018 at approximately 11:00 AM, that the laboratory failed to label all the staining jars used in this staining process for their content and expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation of the regents used for mycology and an interview with the clinical consultant, the laboratory failed to discontinue the use of expired mycology reagents and laboratory reagents. FINDINGS: It was confirmed with the clinical consultant on January 30, 2018 at approximately 11:30 AM that the following eye wash and KOH reagents in use in the laboratory had expired on: August 2016 - CH3114 - Eye Wash October 2016 - Lot K13a33 - KOH August 2017 - Lot K148m1 - KOH
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records, observation and interview with the technical consultant and Moh's processor, the laboratory director failed to provide overall management and direction for the laboratory and ensure that: 1. No eating or drinking took place in the laboratory. Refer to D6011 2. The QA policies are maintained. Refer to D6021 3. Documentation of training was available for the Moh's processor. Referto D6029
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and confirmed in an interview with the clinical consultant

	/laboratory testing person, the director must provide a safe environment in which employees are protected from physical, chemical and biological hazards. Refer to D3011
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 a review of records, surveys observation and an interview with the laboratory director on January 18, 2018 at approximately 11:35 AM, the laboratory director failed to ensure that the QA program for histology pathology testing was maintained to ensure quality laboratory services. Refer to: D5217, D5301, D5403, D5415 and D5417
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on this surveyor's review of educational records and an interview with the Moh's processor, the laboratory director failed to ensure that one of two Moh's processors failed to have documentation of training prior to perform the processing of patients specimens for the Moh's surgery slides.