Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0105786	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Center For Dermatology	128 Columbia Turnpike, 2nd Floor, Florham Park, NJ	

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
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 surveyor review of the Procedure Manual (PM) and interview with the Nurse Manager (NM), the laboratory failed to have all procedures needed for Potassium Hydroxide (KOH) tests from 2/5/19 to the date of the survey. The findings include: 1. The laboratory failed to have a procedure for Quality Control for KOH testing. 2. The NM confirmed on 8/19/21 at 10:00 am that the laboratory did not have the above procedure.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of the Quality Control (QC) records and interview with the Nurse Manager (NM), the laboratory failed to perform and document quality control for Potassium Hydroxide tests from 2/5/19 to the date of the survey. The finding includes: 1. The laboratory did not perform QC on each day of patient testing. 2. The laboratory ran and reported approximately 75 patient samples a year. 3. The NM confirmed on 8 /19/21 at 10:00 am that the laboratory did not perform and document QC on each day of patient testing.