Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0105786	10/10/2023
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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain NJCLL for calendar year 2023. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 10/10/23 that the laboratory did not have a NJCLL license for 2023.
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 surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Laboratory Manager (LM) the laboratory failed to have established written procedures for assessing the competency of Testing Personnel (TP) from 8/19/21 to the date of survey. The findings include: 1. There was

	no written procedure or policy for how to assess the competency of new employees and the annual competency of TP. 2. The LM confirmed on 10/10/23 at 1:30 pm the laboratory failed to establish written policies and procedures for CA.
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 Laboratory Manager (LM) the laboratory failed to have all applicable procedures for Mycology Tests performed from 8/19/21 to the date of survey. The findings include: 1. The laboratory failed to have a written procedure indicating the specific organisms that are to be used as positive and negative control material. 2. The laboratory failed to have a written procedure for verifying quality control material that was obtained from patient specimens. 3. The laboratory failed to have a written procedure for corrective action for false positives from DTM cultures read after 14 days. 4. The laboratory failed to have a written procedure indicating the frequency DTM cultures are read and when Mycology cultures are finalized. 5. The LM confirmed on 10/10/23 at 2:35 pm that the PM did not have all applicable procedures for all Mycology testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer Package Insert (MPI), Test Reports (TR) and Interview with Laboratory Manager (LM), the laboratory failed to follow the MPI for ACU-Derm-(Dermatophyte Test Medium) DTM used for Mycology testing

	from 6/27/18 to the date of the survey. The findings include: 1. The MPI stated "Color interpretation of test is questionable after 14 days due to the possibility of false positives." 2. 3 out of 4 DTM test reports show the final result read after 14 days. 3. The laboratory performed approximately 100 Mycology tests annually. 4. The LM confirmed on 10/10/23 at 2:45 pm that the laboratory did not follow the MPI.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Manager (LM), the laboratory failed to establish or verify the criteria for acceptability of all QC materials before use for ACU-Derm Dermatophyte Test Media (DTM) used for Mycology tests from 8/19/21 to date of survey. The findings include: 1. The laboratory used positive patient specimens to meet the control requirements for DTM. 2. There was no documented evidence the organisms used as QC material was evaluated in accordance with 493.1256(d)(10)(iii). 3. The LM confirmed on 10/10/23 at 2:00 pm the laboratory failed to establish or verify the criteria for acceptability of all QC materials before use.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Manager (LM), the laboratory failed to check each batch of ACU-Derm Dermatophyte Test Media (DTM) for its ability to inhibit growth from 8/19/21 to the date of the survey. The findings include: 1. The laboratory failed to use at least one

	organsim to confirm the ability of DTM to inhibit organisms. 2. The LM confirmed on 10/10/23 at 1:30pm the laboratory failed to confirm the ability of DTM to inhibit organisms. Note. This deficiency was previously cited on 2/5/19
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to establish a Quality Control (QC) program for Mycology testing from 8/19/21 to the date of survey. The findings include. 1. The LD failed to ensure the quality control program was established and maintained. Cross refer D5469 and D5477. 2. The LM confirmed on 10/10/23 at 2:00 pm that the QC program was not established and maintained.