

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0685717	(X3) Date Survey Completed 01/26/2023
Name of Provider or Supplier Dermatology And Skin Cancer Center	Street Address, City, State 11161 New Hampshire Avenue, Suite 307, Silver Spring, MD	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory did not have written procedures for dermatophyte testing with dermatophyte test media (DTM). Findings: 1. It was observed that the laboratory did not have a written procedure for DTM testing and this was confirmed during interview the afternoon of the day of survey. 2. The laboratory may use the package insert for the DTM testing, but the director will need to save this insert and document approval and any changes to the procedures. 3. The laboratory must include the following instructions as part of</p>

the written procedure (even if the manufacturer's package insert is used as the laboratory's procedure): a) Instruction to identify the patient prior to culture b) Instruction to take a specimen from the patient for culture c) Instruction to label the culture (DTM) tube with patient information d) Instruction to identify where the culture will be placed for incubation, how the cap should be fastened on the culture and how long the culture will be incubated and when it should be observed for growth or no growth during that incubation e) Instructions to interpret culture results, record and report patient test results f) Instruction for receipt of DTM into the laboratory, including to place the manufacturer's quality control sticker in the patient log book, date, initial receipt of the DTM in the log and record that the appearance of the media met the laboratory's observations to ensure that the media was not defective or contaminated in the log g) Instructions for reading the room temperature (culture space) and refrigerator temperature (storage space) and documenting the temperatures and also performing and documenting corrective action if a temperature reading fails to meet the laboratory's criteria for acceptability. The procedure also needs to define the acceptable temperature range, and ensure that the laboratory uses a thermometer that has been approved for laboratory use (certified) h) Procedures to train and orient testing staff to the laboratory, and document the training i) Procedures to check staff competency at 6 months and 12 months after training and annually thereafter (checks must be by observation of staff, checking how records are maintained by staff (log book, stickers and receipt of media, entering patient results, temperature recordings as example) j) Quality assurance procedures to document and investigate problems associated with DTM testing

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on interview and observation, the laboratory did not measure and record the room temperature and the refrigerator temperature to ensure testing and storage conditions meet manufacturer requirements for dermatophyte test media cultures. Findings: 1. The laboratory performs dermatophyte testing by incubating patient specimens cultured on dermatophyte test media (DTM) at room temperature. The laboratory did not monitor and did not keep a record of the room temperature to ensure it met the manufacturer's acceptable temperature range to incubate cultures. 2. The laboratory stores DTM culture media in the refrigerator, The laboratory did not monitor and did not keep a record of the refrigerator temperature to ensure it met the manufacturer's acceptable temperature range for storage of culture media. 3. The findings were confirmed with the laboratory director during interview at 12:30 p.m. on the day of survey.

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 interview and review of quality control records, the laboratory did not record the physical characteristics of the dermatophyte test media for each batch and lot of dermatophyte test media (DTM) it received. Findings: 1. The laboratory performs dermatophyte testing using tubes of DTM. The manufacturer provides a sticker in the box of each lot of media it ships. This sticker shows that the manufacturer performed quality control checks for that lot of media the laboratory receives. 2. The laboratory places the manufacturer's sticker in the patient test log on the date the media was received. 3. The laboratory did not document the number of boxes received and did not document that each of the following physical characteristics was met for each shipment of media received. a) cracked tubes b) contamination of test media c) dried or frozen or melted media d) leakage e) proper labeling by the manufacturer f) any other physical characteristics the laboratory requires upon observation 4. The laboratory did not have an individualized quality control plan for performing media checks instead of the laboratory having to perform the same checks as the manufacturer. 5. These findings were confirmed during interview with the laboratory director at 12:00 p.m. on the day of survey.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on interview and observation, the laboratory director did not have competency checks for the medical assistant (MA) performing dermatophyte testing using dermatophyte test media (DTM). Findings: 1. The laboratory director stated that the MA performed DTM testing. 2. It was observed that the laboratory did not have competency check records for the testing person. 3. This was confirmed during interview with the laboratory director on the afternoon of the day of survey.