Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0685717	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And Skin Cancer Center	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
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 review of the "Acu-DTM" information for use (IFU), patient worklog, and interview with the testing person (TP) and laboratory director (LD), the laboratory failed to follow the manufacturer's instructions for performing and reporting dermatophyte screening test results and performing quality control with each new batch of media received into the laboratory. Findings: 1. The "Results" section of the IFU product insert states "The test medium may be examined for color change from yellow to red after 24 hours. Most pathogenic dermatophytes will produce full color change in 3-7 days. The medium should be observed frequently during this period to determine that the color change is concurrent with colony growth. Certain non-dermatophytes may on occasion, turn the medium red, but usually only after full colony growth. Color interpretation of test is questionable after 14 days sue to the possibility of false positives." 2. The patient worklog for dermatophyte screening from 01/27/2023 through 05/15/2024 was reviewed for completion dates. Seven patients were reported as positive after the 14 day limit for interpretation. 3. The "Quality Control" section of the IFU product insert states "CLIA requires the end user to perform a minimum of a positive and negative control on each new lot or batch purchased." 4. The laboratory records show that from 01/08/2023 through 05/15/2024 the laboratory received 2 new lots of "Acu-DTM" media. Lot# D-1504-0923, Expires 2025-09-20 and Lot# D-1474-0822, Expires 2024-08-30. The LD stated that she would use a positive patient as the positive quality control when new Acu-DTM

	media was received. The laboratory records fail to include the date the new lots were put into use showing that the positive and negative controls were tested prior to the new media being put into use for patient testing. 5. During the survey on 05/15/2024 at 11:45 AM, the TP confirmed that the positive patients were being reported after 14 days of incubation and that the positive and negative controls were not being tested on each new lot of media prior to being used for testing and reporting patient test results.
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 review media worksheets and interview with the testing person (TP), the laboratory did not check each batch of "Acu-DTM" agar for sterility, the ability to support growth and inhibit growth of specific organisms prior to use for patient testing. Findings: 1. Review of the media worksheets for 01/27/2023 through 05/15/2024 showed that the laboratory did not check the "Acu-DTM" agar for sterility, the ability to support growth and inhibit growth of specific organisms prior to use for patient testing. 2. During the survey on 05/15/2024 at 11:45 AM, the TP confirmed that the "Acu-DTM" agar was not checked for sterility, the ability to support growth and inhibit growth of specific organisms prior to use for patient testing. The laboratory had not completed an Individual Quality Control Plan (IQCP) and risk assessment to eliminate the end user quality control requirements of checking the sterility of the agar, the ability to support growth and inhibit growth of specific organisms prior to use for patient testing.
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 review of the evidence of compliance (EOC) submitted for the previous recertification survey conducted on 01/26/2023, laboratory records, procedure manuals, and interview with the testing persons (TP), the laboratory director (LD)

	failed to ensure that the submitted procedures had been added to the procedure manual and the competency checks on the TP performing the dermatophyte interpretations was available at the time of the survey. Findings: 1. The EOC that was received on 04 /16/2024 included a notation at the bottom of the "Media QC [quality control] Form" stating "I have trained and observed the medical assistant performing her tasks, and can attest to the fact that she is competent in her lab duties." The LD's signature was after the statement. The documentation failed to include the name of the medical assistant and the date of the evaluation. The supporting documentation also included a sheet of paper labeled "Procedure for Performing Testing with DTM." The procedure failed to include the approval signature of the LD, the date the procedure was approved, and that the TP had been trained on the updated procedures. 2. The "Media QC Form" worksheets and other laboratory records that were reviewed at the time of the survey failed to include competency evaluation that was submitted as part of the EOC. The "Procedure for Performing Testing with DTM" procedure was not in the binder that included the other procedures for the laboratory. 3. The policies and procedure manual failed include a procedure and worksheet for documenting the competency of the TP. 4. During the survey on 05/15/2024 at 11:45 AM, the TP confirmed that there were no procedure for the competency in the procedure manual and was not aware of the documents submitted to the state as part of the EOC.