Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0696981	12/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dupage Medical Group - Dermatology	199 Town Square, Wheaton, IL	

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
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 of laboratory policies and procedures, the manufacturer's instructions for use (IFU), laboratory records, patient results, lack of documentation, direct observation, and interview with a laboratory representative; the laboratory failed to check each lot of Dermatophyte Test Medium (DTM) for its ability to inhibit fungal growth for four of four patient results reviewed in the years of 2023 through the date of survey, 12/19/2024, in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Dermatophyte Test Medium [DTM] Protocol", which stated, under "Control", "All new lots of DTM medium will be tested by culturing with a known dermatophyte ...." 2. Review of the Hardy Diagnostics' DTM IFU revealed, under "User Quality Control [QC]", "End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies .... Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable." 3. Upon of tour of the laboratory on 12/19/2024, at 11:37 am, direct observation revealed the following KWIK-STIK quality control organisms in the storage refrigerator: a. Candida albicans ([American Type

	Culture Collection] ATCC: 10231) b. T. interdigitale (ATCC: 9533) 4. Review of laboratory quality control records for fungal testing revealed the laboratory was only performing positive quality control testing to determine growth, using Candida albicans (ATCC: 10231), and biochemical response, using Trichophyton species (ATCC: 9533), for ten of ten Hardy Diagnostics' DTM lot numbers in use from the beginning of 2023 to the date of survey, 12/19/2024. Lot: Date tested: C. albicans: T. species: 511561 09/27/2022 Growth Color change 513921 01/12/2023 Growth Color change 519018 01/26/2023 Growth Color change 526071 05/12/2023 Growth Color change 601050 09/05/2023 Growth Color change 612127 10/17/2023 Growth Color change 442923 02/15/2024 Growth Color change 442952 06/04/2024 Growth Color change 629481 08/29/2024 Growth Color change 640407 10/04/2024 Growth Color change 5. Review of four of four patient results for DTM fungal cultures found no quality control results demonstrating negative, or inhibition of fungal growth, for the lot numbers of DTM used. Patient: DTM Lot: Date of testing: GE11283913 511561 1 /18/2023 GE11695561 519018 4/25/2023 GE37793064 526071 9/13/2023 GE11727028 612127 1/12/2024 6. Interview with a laboratory representative on 12/19 /2024, at 11:47 am, confirmed the laboratory failed to check each lot of DTM for its ability to inhibit fungal growth in the specialty of microbiology.