Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2320093	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Elmhurst Derm	135 N Addison Ave, Elmhurst, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions for use for dermatophyte test medium (DTM), laboratory policies and procedures, laboratory records, the CMS-209 (Laboratory Personnel Report), lack of documentation, direct observation, and interview with the laboratory representative; the laboratory failed to follow manufacturer's instructions for DTM testing by interpreting results of four of four patient tests after the manufacturer's designated 14 day maximum incubation and by failing to document daily DTM examinations (See D5411), failed to monitor and document manufacturer's required conditions essential for proper temperature of storage and testing environments to ensure accurate and reliable test results for two of two lots of DTM utilized (See D5413), and failed to indicate the testing personnel interpreting the quality control results of two of two DTM lots received (See D5465).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 manufacturer's instructions for use (IFU) for dermatophyte test medium (DTM), laboratory policies and procedures, patient testing records, and interview with the laboratory representative; the laboratory failed to follow manufacturer's instructions for DTM testing by interpreting results of four of four patient tests after the manufacturer's designated 14 day maximum incubation and by failing to document daily DTM examinations. Findings include: 1. Review of the manufacturer's IFU revealed, under "Interpretation of Results", "Media should be examined daily for up to fourteen (14) days." 2. Review of the manufacturer's IFU revealed, under "Limitations", "False-positive reactions may result, if interpretations are made beyond 14 days of incubation." 3. Review of laboratory policies and procedures revealed the procedure titled "Dermatophyte Test Medium Protocol", which stated, under "DTM Protocol", "2. Examination ...a. Check bottles once a week." 4. Review of laboratory policies and procedures revealed the procedure titled "Dermatophyte Test Medium Protocol", which stated, under "DTM Protocol", "DTMs take 2-4 weeks to grow." 5. Review of patient testing records revealed the "DTM Log", which documented interpretation of DTM occurring after the manufacturer's designated 14 day maximum incubation. Date of Inoculation: Date of Interpretation: 04/15/2025 05/20/2025 04/22/2025 05/22/2025 06/17/2025 07/17/2025 07/14/2025 [To be interpreted] 6. Interview with the laboratory representative on 08/14/2025, at 12:24 pm, confirmed the laboratory failed to follow manufacturer's instructions for DTM testing by interpreting results of four of four patient tests after the manufacturer's designated 14 day maximum incubation and by failing to document daily DTM examinations.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the manufacturer's instructions for use (IFU) for dermatophyte test medium (DTM), laboratory records, direct observation, lack of documentation, and interview with the laboratory representative; the laboratory failed to monitor and document manufacturer's required conditions essential for proper temperature of storage and testing environments to ensure accurate and reliable test results for two of two lots of DTM utilized from the beginning of testing, 04/12/2025, through the date of survey, 08/14/2025. Findings include: 1. Review of the manufacturer's IFU revealed, under "Storage and Shelf Life", "Storage: Upon receipt store ...[Catalog number] L27 at 2-30[degrees Celsius] away from direct light." 2. Review of the manufacturer's IFU revealed, under "Procedure", "Incubate media at room temperature (15-30[degrees Celsius]) ...." 3. Upon of tour of the laboratory on 08/14 /2025, at 11:39 am, surveyors observed DTM being stored and incubated in a closed

	cabinet in the laboratory at ambient/room temperature. 4. Review of laboratory records revealed a lack of documentation of the monitoring of the ambient/room temperature in the cabinet utilized for DTM storage and incubation. 5. Review of laboratory quality control (QC) records identified two lots of DTM utilized for patient testing from the beginning of testing, 04/12/2025, through the date of survey, 08/14 /2025. DTM Lot #: Date QC performed: L27-648909 04/12/2025 L27-658946 06/20 /2025 6. Interview with the laboratory representative on 08/14/2025, at 11:45 am, confirmed the laboratory failed to monitor and document manufacturer's required conditions essential for proper temperature of storage and testing environments to ensure accurate and reliable test results for two of two lots of DTM utilized from the beginning of testing, 04/12/2025, through the date of survey, 08/14/2025.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) (d)(8) Test control materials in the same manner as patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, laboratory quality control (QC) records, lack of documentation, and interview with the laboratory representative; the laboratory failed to indicate the testing personnel (TP) interpreting the QC results of two of two dermatophyte test medium (DTM) lots received from the beginning of testing 04/12/2025 through the date of survey, 08/14/2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed one individual serving as the laboratory director (LD) and only TP. 2. Review of laboratory policies and procedures revealed the procedure titled, "Dermatophyte Test Medium Protocol", which stated, under "DTM Protocol", "Providers must document interpretation in the DTM log." 3. Review of laboratory policies and procedures revealed the policy titled, "Derm Lab Quality Assessment Policy", which stated, under "Policy", "2. All Quality Control (QC) records (such as log sheets ...) will be reviewed by the Laboratory Supervisor or designated staff. All forms will be signed and dated on the date of review." 4. Review of laboratory QC records revealed a lack of documentation of the provider's interpretation and review of the DTM QC results. DTM Lot #: Date QC performed: L27-648909 04/12/2025 L27-658946 06/20/2025 5. Interview with the laboratory representative on 08/14/2025, at 12:24 pm, confirmed the laboratory failed to indicate the TP interpreting the QC results of two of two DTM lots received from the beginning of testing 04/12/2025 through the date of survey, 08/14/2025.