Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2042650	07/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Dermatology	3736 Atlantic Ave Ste 101, Long Beach, CA	

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) (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 observation of DTM Cultures and review of DTM Culture records, reviews of Hardy Diagnostics manufacturer's Instructions for Use (IFU) for it's DTM (Dermatophyte Test Medium), Catalog number L27, 10 mL Vial, Slant, 20 vials/box; and the laboratory document titled, "DTM Procedure", and interview with Medical /Laboratory Assistant-10/Office Supervisor. it was determined the laboratory failed to follow manufacturer's instructions for quality control and culture incubation time. Findings included: 1. The IFU stated, as follows: a. Storage and Shelf Life: store at 2 -30 degrees C (noninoculated) b. User Quality Control: recommended that "end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform qualtiy control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable". c. Procedure: Incubate up to 14 days. d. Interpretation of Results: Examine daily for up to 14 days e. "False-positive reactions may result if interpretations are made beyond 14 days of incubation." 2. The laboratory instructions titled, "DTM Procedure" failed to follow the IFU, as follows: a. No instructions for storing noninoculated vials. b. No instructions for Quality Controls. c. "Check the vial daily for up to 30 days." 3. DTM Cultures incubating more than the recommended 14 days: Date ID Status on 7/07/26 ---------- 6/02/26 H, A pending at 35 days 6/08/26 T, C pending at 29 days 6/15/26 R, H pending at 22 days 6 /17/26 L, C pending at 20 days 6/22/26 O, J pending at 15 days 4. Three out of six DTM Culture records documented final results were interpreted after the FDA-

	approved 14 days incubation time, as follows: Date ID Date reported ---------- 8/22/23 S, G 9/27/23 1/07/25 C, T 2/19/25 6 /17/25 M, J 7/17/25 5. Medical/Laboratory Assistant-10/Office Supervisor affirmed (7 /07/26 at 4:30 pm) the aforementioned findings. .
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 observation of DTM vials and DTM Cultures, reviews of Hardy Diagnostics IFU and the laboratory document titled, "DTM Procedure", the lack of laboratory records and thermometer, and interview with Medical/Laboratory Assistant-10/Office Supervisor, it was determined the laboratory failed to monitor and document the Temperature that DTM vials were stored and inoculated DTM cultures were incubated. Findings included: 1. DTM vials stored in the original cardboard box and DTM Cultures in a plastic basket were observed on an open shelf. 2. Hardy Diagnostics IFU specified storing noninoculated DTM vials at 2-30 degrees C. 3. The laboratory's "DTM Procedure" instructions specified incubating DTM cultures at 77-86 degrees F. 4. No DTM vials were received in 2024 due to manufactuerer's supply chain issues. For 13 out of 13 DTM Cultures records selected for review from 2023, 2025 and 2026, the laboratory failed to have records for monitoring and documenting temperatures for storing DTM vials and incubating DTM cultures, as follows: Date DTM ID ---------- 8/22 23 S, G 10/23/23 D, S 11/13/23 C, B 11/21/23 T, K 1/07/25 C, T 6/17/25 M, J 12/04/25 T, M 6/02/26 H, A 6/08/26 T, C 6/15/26 R, H 6/17/26 L, C 6/22/26 O, J 6/26/26 L, E 5. Laboratory/Medical Assistant-10/Office Supervisor affirmed (7/07/26 at 4:00 PM) there was no thermometer where the DTM vials were stored or incubated after inoculating with specimen, and that temperatures weren't monitored or recorded. .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: Based on review of the DTM manufacturer's IFU, observation of three different lot numbers of DTM vials, the lack of laboratory records and procedure, and interview

	with Laboratory/Medical Assistant-10/Office Supervisor, it was determined that the laboratory failed to perform quality assurance and quality control procedures on each Lot Number and Shipment of DTM including: documenting the physical characteristics of the DTM vials before use and reporting any deterioration to the manufacturer, checking each lot number and shipment of DTM for sterility and that it can support growth of dermatophyte that causes the color of the agar medium to change from yellow-orange to red. Findings included: 1. Hardy Diagnostics IFU included the section titled, "User Quality Control" that recommended "end users check for signs of contamination and deterioration" and "perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction". 2. The laboratory failed to have records documenting Lot Numbers and Expiration Dates of DTM vials received. 3. The laboratory had three different Lot numbers of DTM vails for current use, as follows: Lot number Expiration Date ---------- 682600 9/19/26 683442 9/27/26 684363 10/07 /26 3. For 3 out of 3 lot numbers of DTM vials, the laboratory failed to have records, as follows: a. Date Received, Lot number, Expiration Date; b. the physical appearance of the vials before use and signs of deterioration such as shrinking, cracking or discoloration, and contamination; c. Positive Control vial that supported the growth of a dermatophyte and turned red; d. Negative Control vial that demonstrated negative reaction, such as growth without changing the color of the agar. 4. Laboratory /Medical Assistant-10/Office Supervisor affirmed (7/07/26 at 3:00 PM) the aforementioned lack of quality assurance and quality control records. 5. Laboratory instructions titled , "DTM Procedure", failed to include instructions for the aforementioned quality assurance and quality control activities and record keeping. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of 13 laboratory records from 2023-2026, and interview with Medical /Laboratory Assistant-10/Office Supervisor, it was determined the laboratory failed to have an ongoing process/procedure to monitor test records for accuracy, identify errors, and make corrections. Findings included: 1. Three of 6 test records from 2026 had issues, as follows: Date ID Test ---------- 6/15/26 R, H DTM Culture; Not recorded in Log Book 6/17/26 L, J Scabies positive; Not recorded in Patient chart 6/26/26 L, E Negative result; Undated, Testing Person Unknown, Not recorded in Patient chart 2. There were no records that the errors had been identified or addressed. 3. Medical/Laboratory Assistant-10/Office Supervisor affirmed the errors (7/07/26 at 4:30 pm) and the lack of a routine process to assess the quality of test records and assure errors were identified and corrected in a timely manner. . .
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic,

	and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the cumulative affect of deficiencies found and cited, the Laboratory Director is herein cited for deficient practice in overseeing all aspects of moderate complexity testing to ensure the quality of preanalysis, analysis, and postanalysis. Findings included: 1. The laboratory failed to follow manufacturer's Instructions For Use. See D5411. 2. The laboratory failed to monitor temperatures. See D5413. 2. The laboratory failed to perform and document Quality Control procedures. See D5477. 3. The laboratory failed to monitor laboratory records to ensure quality and compliance. See D5791. .