

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0975875	<b>(X3) Date Survey Completed</b>  08/23/2023
<b>Name of Provider or Supplier</b>  Robin M Schaffran Md	<b>Street Address, City, State</b>  8920 Wilshire Blvd Ste 545, Beverly Hills, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Fungal Cultures Log Book, the storage refrigerator, and the cupboard for incubating cultures, review of records, the lack of records, and interview with an administrator, the laboratory failed to monitor and document the temperature where the DTM (Dermatophyte Test Medium) were stored and where the inoculated fungal cultures were incubated. Findings included: 1. The Fungal Cultures Log Book included the manufacturer's instructions for Healthlink DTM (Dermatophyte Test Medium) with specific temperature requirements: "Culture media should be stored at 2 - 25C (36 - 77F)" and incubated at 22 - 30C. 2. For 11 out of 11 cultures, five in 2022 and six in 2023, the laboratory failed to have records monitoring and documenting the temperatures of the storage refrigerator and the incubation cupboard. 3. The administrator affirmed (8/23/23 at 11:30 AM) the aforementioned findings. 4. The reliability and quality of Negative results reported for the DTM cultures could not be assured. Two selected at random were inoculated on 3/04/22 and 7/14/23. .</p>
<b>D5477</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p>

(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 fungal cultures records, the lack of records, and interview with the administrator, the laboratory failed to document DTM Lot numbers and Expiration dates, dates received, that each batch and shipment was checked for sterility /contamination, discoloration, breakage, and ability to support growth of dermatophytes and produce biochemical response. Findings included: 1. The Fungal Cultures Log Book for 2022 and 2023 had no quality control records. 2. The administrator affirmed (8/23/23 at 11:30 AM) the laboratory had no records documenting QC for fungal cultures. 3. For 11 of 11 fungal cultures in 2022-2023, the reliability and quality of results reported for DTM cultures could not be assured. .

**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. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the failure to perform and document quality control activities and monitor temperatures affecting DTM fungal cultures for 2022 and 2023, the laboratory failed to establish and follow written policy/procedure for an ongoing process to monitor, assess, identify, and correct errors in the analytic system. See D5413 and D5477. .

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the cumulative nature of noncompliance cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure quality assessment activities were established and maintained to assure the quality of DTM fungal cultures. See D5791.