

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0694770	<b>(X3) Date Survey Completed</b>  11/22/2022
<b>Name of Provider or Supplier</b>  Gregory Herbich Md	<b>Street Address, City, State</b>  1003 Bishop St #390, Honolulu, HI	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Potassium Hydroxide (KOH) examination and Hardy Diagnostics Dermatophyte Test Medium (DTM) culture records, and an interview with the Laboratory Director on 11/22/2022 at 11:45 a.m., the laboratory failed to twice annually verify the accuracy of its KOH and DTM testing. The laboratory performs approximately 21 KOH examinations and DTM cultures annually. The findings included: a. The laboratory verified the accuracy of its KOH and DTM testing once in 2020, once in 2021 and once in 2022 with the Laboratory Director of another CLIA certified dermatology laboratory. Accuracy records consisted only of the Laboratory Director's initials and a review date.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review, direct observation and interview with the laboratory director</p>

on 11/22/2022, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in CFR 493.1289 for the mycology subspecialty testing it performed. The findings included: a. The laboratory failed to verify at least twice annually the accuracy of its KOH examinations and DTM culture testing. See D5217. b. The laboratory failed to follow Hardy Diagnostics DTM Instructions for Use Procedure instructions. See D5413. c. The laboratory failed to follow Hardy Diagnostics DTM Instructions for Use User Quality Control instructions. This is a repeat deficiency cited during the 04/17/2018 and 01/06/2021 surveys. See D5477. d. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in its analytic systems. This is a repeat deficiency cited during the 04/17/2018 and 01/06/2021 surveys. See D5791.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(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: (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.

This STANDARD is not met as evidenced by:  
Based on a review of Hardy Diagnostics DTM culture records and direct observation of patient testing on 11/22/2022 at 11:15 a.m., the laboratory failed to follow Hardy Diagnostics DTM Instructions for Use, Procedure instructions to incubate inoculated patient media at room temperature (15-30 degrees C). The findings included: a. A patient DTM culture observed incubating on top of a file cabinet in the office records section revealed that laboratory failed to monitor and document room temperatures. b. Office staff stated during an interview on 11/22/2022 at 11:25 a.m. that daily room temperatures were not taken.

**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 a review of the DTM Fungal Culture Quality Control log and an interview with the Laboratory Director on 11/22/2022 at 11:40 a.m., the laboratory failed to follow the Hardy Diagnostics DTM Instructions for Use, User Quality Control instructions to check 6 of 6 lots of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response.

	<p>The findings included: a. The laboratory failed to demonstrate inhibition or a negative reaction for DTM media lot #s L27471865, L2747329, L27485694, L27491191, L27494925, and L27507335 used between 03/27/2021 and 11/22/2022. b. The laboratory failed to perform quality control on DTM media lot # L2747329 before its 2/28/2021 expiration date. * This is a repeat deficiency. The laboratory was cited for this deficiency during its 04/17/2018 survey and 01/06/2021 survey.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the DTM Fungal Culture Quality Control log and an interview with the Laboratory Director on 11/22/2022 at 11:40 a.m., the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in CFR 493.1251 through 493.1283. See D5477. * This is a repeat deficiency. The laboratory was cited for this deficiency in its 04/17/2018 survey and 01/06/2021 survey.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the Hardy Diagnostics DTM test system and an interview with the Laboratory Director on 11/22/2022 at 11:40 a.m., the Laboratory Director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. See D5791. *This is a repeat deficiency. The laboratory was cited for this deficiency in its 04/17/2018 survey and 01/06/2021 survey.</p>
<p><b>D6022</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on record review and direct observation on 11/22/2022, and an interview with the Laboratory Director on 11/22/2022 at 11:45 a.m., the Laboratory Director failed to ensure that the quality assessment program is established and maintained to identify failures in quality as they occur. 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, accurately and proficiently and for assuring compliance with the applicable regulations. See D5217 and D5413.