

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0694770	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Gregory Herbich Md	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2043	<p>MYCOLOGY CFR(s): 493.827(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Association of Bioanalysts (AAB) proficiency testing records and an interview with the laboratory director on 5/22/2024 at 12:15 PM, the laboratory failed to return its Nonchemistry M1 2024 Dermatophyte Culture results within the time frame specified by the program resulting in a score of 0 for the testing event. The laboratory director stated that culture results for Specimens 1, 2, 3, 4, and 5 were not available for reporting by the program deadline. The laboratory performed 18 dermatophyte cultures annually.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of three of three 2023 AAB Nonchemistry Dermatophyte Culture and KOH slides proficiency testing program evaluations and an interview with the laboratory director on 5/22/2024 at 12:15 PM, the laboratory failed to review and evaluate its proficiency testing performance. The laboratory performed 18 dermatophyte cultures annually. The findings include: 1. The laboratory reported an incorrect response for Specimen 4 in the 2023 AAB Nonchemistry M1 dermatophyte</p>

culture testing event. The intended response was *Trichophyton rubrum* (Dermatophytes present). The laboratory reported Negative (Dermatophytes absent). 2. The laboratory reported incorrect responses for Specimen 6 and Specimen 10 in the 2023 AAB Nonchemistry M2 dermatophyte culture testing event. The intended response for Specimen 6 was Negative (Dermatophytes absent). The laboratory reported Positive (Dermatophytes present). The intended response for Specimen 10 was *Trichophyton verrucosum* (Dermatophytes present). The laboratory reported Negative (Dermatophytes absent). 3. The laboratory reported an incorrect response for Specimen 12 in the 2023 AAB Nonchemistry M3 KOH testing event. The intended response was Positive. The laboratory reported Negative. 4. The laboratory director stated the laboratory failed to return its AAB Nonchemistry M1 2024 Dermatophyte Culture results for Specimens 1, 2, 3, 4, and 5 within the time frame specified by the program resulting in a score of 0 for the testing event. 5. The laboratory director stated proficiency testing program evaluation activities to include corrective actions were not performed.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of AAB proficiency testing records and an interview with the laboratory director on 05/22/2024 at 12:15 PM, the laboratory director failed to ensure its Nonchemistry M1 2024 Dermatophyte Culture results were returned within the time frame established by the proficiency testing program. Refer to D tag D2043.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on a review of three of three 2023 AAB Nonchemistry Dermatophyte Culture and KOH slides survey evaluations and an interview with the laboratory director on 5/22/2024 at 11:45 AM, the laboratory director failed to ensure an approved corrective action plan was followed for the laboratory's incorrect and/or late proficiency testing results. Refer to D tag D5211.