

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0694770	(X3) Date Survey Completed 07/01/2026
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: The surveyor's review of potassium hydroxide (KOH) accuracy verification records, and an interview with 1 of 1 facility personnel revealed the laboratory failed to verify the accuracy of its KOH slide examinations at least twice annually in 2025. The findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of its KOH slide examinations at least twice annually in 2025. 2. The facility personnel interviewed on 7/1/2026 at 10:00 AM confirmed KOH accuracy verifications were performed once during 2025. 3. The laboratory performed an annual volume of 5 KOH slide examinations.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: The surveyor's review of American Association of Bioanalysts (AAB) Dermatophyte Culture proficiency test (PT) records, the lack of documentation, and an interview with 1 of 1 facility personnel revealed the laboratory failed to document its review and corrective actions for missing 2025 Dermatophyte Test Medium (DTM) Event 1 PT results. The findings include: 1. No documentation was presented for review to indicate the laboratory participated in the 2025 AAB Dermatophyte Culture PT Event 1. An evaluation of the laboratory's results for 5 of 5 PT specimens M1, M2, M3, M4,

	and M5 was not included in the AAB Medical Laboratory Evaluation (MLE) participant report. 2. The facility personnel interviewed on 7/1/2026 at 10:20 AM stated the laboratory was not aware its Event 1 PT results were not evaluated by the AAB proficiency testing program.
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: The surveyor's review of Quality Control Analysis of Dermatophyte Culture Logs, direct observation, and an interview with 1 of 1 facility personnel revealed the laboratory failed to document the identity of the control organisms it used to check each shipment of the Hardy Diagnostics Dermatophyte Test Medium (DTM) it received in 2024, 2025, and 2026. The findings include: 1. The laboratory received 5 DTM shipments between 2024 and 2026: Lot L27-635159 received 9/25/2024 expiration 1/13/2025 Lot L27-645062 received 2/28/2025 expiration 5/12/2025 Lot L27-661175 received 7/25/2025 expiration 12/6/2025 Lot L27-675748 received 2/17/2026 expiration 6/13/2026 Lot L27-664487 received 5/20/2026 expiration 10/27/2026 2. Quality control was performed on each shipment by inoculating 5 organisms onto individual DTM culture slants. A positive (+) or negative (-) reaction for each DTM slant was recorded on Quality Control Analysis of Dermatophyte Culture Logs forms. The identity of each organism used for quality control testing was not documented on 5 of 5 Quality Control Analysis of Dermatophyte Culture Logs forms. 3. The facility personnel interviewed on 7/1/2026 at 10:50 AM stated quality control testing swabs saved from previous AAB PT events were kept in the laboratory refrigerator. Direct observation of the refrigerated swabs revealed no identifying information on the packaging to indicate the identity of the organisms, proper storage conditions, and expiration dates. 4. The laboratory performed an annual volume of 11 DTM tests.
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: The surveyor's review of KOH accuracy verification records, AAB dermatophyte culture PT records, dermatophyte culture quality control logs, direct observation, and an interview with 1/1 facility personnel revealed the laboratory failed to establish policies and procedures to monitor, assess, and correct problems identified with its mycology testing services from 9/1/2024 through 6/30/2026. The findings include: 1. The laboratory failed to twice annually verify the accuracy of its KOH slide

examinations during 2025. See D tag D5217. 2. The laboratory failed to investigate its missing 2025 AAB Dermatophyte Culture PT Event 1 test scores. See D tag D5221. 3. The laboratory failed to document the identity of the organisms it used to quality control 5 of 5 DTM media shipments received in 2024, 2025, and 2026. See D tag D5477. 4. The laboratory performed an annual volume of 5 KOH slide examinations and 11 DTM tests.