Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0720185	08/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dylan E Lee, Md Inc	1380 Lusitana St Ste 401, 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 laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed the laboratory failed to twice annually verify the accuracy of its direct wet mount preparations, potassium hydroxide (KOH) preparations, and Accuderm dermatophyte test medium (ACU-DTM) testing in 2022 and 2023. The laboratory performed an annual volume of 125 direct wet mount and KOH preparations, and 20 ACU-DTM tests.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed the laboratory failed to have a written procedure for the ACU-DTM testing it performs. The laboratory performed an annual volume of 20 ACU-DTM tests.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: The surveyor's review of the laboratory procedure manual and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed that the laboratory failed to have the current laboratory director approve, sign, and date its American Academy of Dermatology CLIA '88 Laboratory Manual (Dermatology Practice Administration). This manual was last signed in October 1993 by the previous laboratory director.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: The surveyor's review of laboratory maintenance records and an interview with the laboratory office staff on 08/02/2024 at 9:30 AM revealed the laboratory failed to follow its maintenance procedures for the Swift Instruments International S.A. microscope, Model M1000-D, Serial Number 8550764. The laboratory performed an annual volume of 125 direct wet mount and KOH preparations. The findings include: 1. The Equipment Quality Control-Microscope section of the laboratory manual listed the following maintenance activities to perform: 1) Microscope stage and ocular eye pieces are to be cleaned and 2) Grounding check is monitored. 2. The laboratory office staff documented performing the following maintenance activities on their Microscope Daily Cleaning Checklist Canton City Health District form, i.e., 1) Use lens cleaning fluid on lenses tissue to wipe lenses of dust or oil and 2) Replace Dust Cover. The laboratory office staff states that grounding checks are not performed and could not confirm the identity of the Canton City Health District.
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: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/0/2024 at 9:00 AM revealed the laboratory failed to check each batch of ACU-DTM for its physical characteristics, sterility, and its ability to support growth before or concurrently with initial use. The laboratory performed an annual volume of 20 ACU-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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed the laboratory failed to follow its Quality Assurance (QA) Program General Quality Policies to ensure problems identified in the analytic systems are corrected and documented. The findings include: 1. The laboratory failed to twice annually verify the accuracy of the direct wet mount preparations, potassium hydroxide (KOH) preparations, and ACU-DTM it performed in 2022 and 2023. Refer to D tag D5417. 2. The laboratory failed to have a written procedure for the ACU-DTM testing it performs. Refer to D tag D5401. 3. The laboratory failed to have the current laboratory director approve, sign, and date its American Academy of Dermatology CLIA '88 Laboratory Manual (Dermatology Practice Administration). Refer to D tag D5407. 4. The laboratory failed to follow its maintenance procedures for its Swift Instruments International S.A. microscope, Model M1000-D, Serial Number 8550764. Refer to D tag D5433. 5. The laboratory failed to check each batch of ACU-DTM it received before or concurrently with the initial use. Refer to D tag D5477.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:30 AM revealed the current laboratory director failed to ensure its quality control program was maintained to ensure the quality of the ACU-DTM testing it performed. The laboratory failed to check each batch of ACU-DTM it received before or concurrently with initial use. Refer to D tag 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: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed the current laboratory director failed to ensure that its quality assessment program was maintained to assure the quality of laboratory services provided. The findings include: 1. The laboratory failed to follow its Quality Assurance (QA) Program General Quality Policies to ensure problems identified in its analytic systems are corrected and documented. Refer to D tag D5791. 2. The laboratory Quality Assurance (QA) Program Quality Control Assessment states "The Laboratory Director reviews all quality control charts and logs on at least a monthly basis". Prior and current laboratory director review of laboratory refrigerator temperature logs, room temperature logs, and the Microscope Daily Cleaning Checklist Canton City Health District logs was not documented for 2022, 2023, and 2024.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the current laboratory director on 08/02/2024 at 9:00 AM revealed the current laboratory director failed to ensure an approved procedure manual is available for any aspect of the testing process. The finidings include: 1. The laboratory failed to have a written procedure for the ACU-DTM testing it performs. Refer to D tag D5401. 2. The laboratory failed to have the current laboratory director approve, sign, and date its American Academy of Dermatology CLIA '88 Laboratory Manual (Dermatology Practice Administration). Refer to D tag D5407.