

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0720185	(X3) Date Survey Completed 04/26/2019
Name of Provider or Supplier Dylan E Lee, Md Inc	Street Address, City, State 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
D5413	<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 a 04/26/2019 review of laboratory quality control records and an interview with the Laboratory Director at 3:00 p.m., the laboratory failed to define temperature criteria for accurate and reliable test system operation. The findings include: 1. The Accuderm, Inc. Dermatophytic Test Medium (DTM) Directions for Use states to incubate inoculated medium vials at "room temperature 20-30 degrees Celsius". Decreased temperatures may result in slower growth and optimal growth occurs at 29oC. 2. The Laboratory Director stated that the temperature of the room where DTM vials are incubated is not monitored. Inoculated DTM vials are read on day 14. Air conditioning in the office building is turned off between 6:00 p.m. to 06:00 a.m. each day. 3. The laboratory performed 43 DTM tests in 2018.</p>
D6010	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)</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</p>

director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on a 04/26/2019 review of laboratory quality control records and an interview with the Laboratory Director at 15:00 p.m., the laboratory failed to ensure that the environmental conditions of the laboratory are appropriate for the DTM testing it performs. Refer to D tag 5413.