Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0694770	04/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gregory Herbich Md	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
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 review of Dermatophyte Test Medium (DTM) records and interview with the laboratory director on 4/17/18, the laboratory failed to 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 document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. Findings included: a. The laboratory used DTM media to culture patient specimens and detect the presence of dermatophyte fungi. DTM media Lot# 1612512 was used to test 10 patients from 8/30/16 to 11/29/16. DTM media Lot# 172331 was used to test 9 patient specimens from 11/25/17 to 2/26/18. There was no record at the time of the survey that these two lot numbers had been checked to support the growth of dermatophyte fungi and produce the red pigment as a biochemical response. b. DTM media Lot numbers 1723313, 171214, 1628707, 1620018, and 1612512 were used to test 69 patients specimens from 5/12/16 to 2/26 /18. There was no documentation that the physical properties of the media had been checked for deterioration upon receipt by the laboratory.
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: Based on review of Dermatophyte Test Medium records and interview with the laboratory director on 4/17/18, the laboratory failed to establish and follow written written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct identified in the analytic systems specified in 493.1251 through 493.1283. Findings included: The laboratory did not have written polices and procedures to ensure that each lot number of DTM was tested for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. See 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: Based on review of Dermatophyte Test Medium records and interview with the laboratory director on 4/17/18, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. Findings included: The laboratory failed to 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 document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. See D5477.