Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0694770	01/06/2021
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 a review of Dermatophyte Test Medium (DTM) records and an interview with the Laboratory Director on 01/06/2021 at 09:30 a.m., 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. The findings include: a. The laboratory used DTM media to culture patient specimens to detect the presence of dermatophyte fungi. DTM media Lot# 1723313 was used to test 7 patients from 01/18/2018 to 02/26/2018. DTM media Lot# 1725712 was used to test 8 patients from 03/07/2018 to 05/22/2018. DTM media Lot# 1806609 was used to test 17 patients from 08/13/2018 to 02/20 /2019. DTM media Lot# 1901010 was used to test 6 patients from 03/13/2019 to 01/02 /2020. DTM media Lot# L27445884 was used to test 3 patients from 12/14/2019 to 02 /14/2020. DTM media Lot# L27461475 was used to test 5 patients from 08/21/2020 to 11/12/2020. Documentation that these six lot numbers had been checked to support the growth of dermatophyte fungi and produce the red pigment as a biochemical response was not available for review at the time of the survey. b. DTM media Lot #s 1723313, 1725712, 1806609, 1901010, L27445884 and L27461475 were used to test 46 patient specimens from 01/18/2018 to 11/12/2020. Documentation that the

	physical properties of the media had been checked for deterioration upon receipt was not available for review at the time of the survey. c. This is a repeat deficiency. The laboratory's 06/08/2018 corrective action for D5477 stated "Plan is to implement testing by an outside CLIA certified lab for red positives, white growth negatives and no growth tests. Minimally one of each per lot will be sent to another lab". The Laboratory Director stated that one red positive specimen, one white growth negative specimen and one no growth specimen were not sent to another laboratory for testing.
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 a review of Dermatophyte Test Medium (DTM) records and an interview with the Laboratory Director on 01/06/2021 at 09:30 a.m., the laboratory failed to 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 CFR 493.1251 through 493.1283. The findings include: a. The laboratory did not have written policies and procedures to ensure that each lot number of DTM was tested for its ability to support growth and as appropriate, select or inhibit 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 b. This is a repeat deficiency.
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 a review of Dermatophyte Test Medium (DTM) records and an interview with the Laboratory Director on 01/06/2021 at 09:30 a.m., the laboratory failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. The findings include: a. The laboratory failed to check each batch of DTM 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. b. This is a repeat deficiency.