Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D1014640	10/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
John D Boyer, Md Inc	1329 Lusitana St, Suite 501, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, direct observation and an interview with office staff on October 2, 2021 at 3:30 PM, it was determined that the laboratory failed to define criteria for conditions that are essential for proper storage of its Leica melanoma testing reagents. The findings include: 1. Leica manufacturer instructions provided the following storage temperatures for melanoma testing reagents: a. PowerVision Poly-HRP anti-Mouse IgG; 2 - 8 degrees C b. PowerVision Universal IHC Blocking Diluent; 2 - 8 degrees C c. PowerVision DAB Chromagen Solution; 2 - 8 degrees C d. PowerVision DAB Substrate Solution; 2 - 8 degrees C 2. Melanoma testing reagents were stored in a refrigerator where temperatures were not monitored a. PowerVision Poly-HRP anti-Mouse IgG; Lot 6082927, opened date 8/9/2021, expiration date 6/2022 b. PowerVision Universal IHC Blocking Diluent; Lot 6082927, opened date 8/1/2021, expiration date 6/2022 c. PowerVision DAB Chromagen Solution; Lot 6084737, opened date not recorded, expiration date 8/2022 d. PowerVision DAB Substrate Solution; Lot 6084737, opened date not recorded, expiration date 8/2022 3. The office staff confirmed that the refrigerator did not have a temperature monitoring device 4. The laboratory tested 55 melanoma patients in 2019, 48 patients in 2020 and 35 patients in 2021 to date

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, direct observation and an interview with office staff on October 2, 2021 at 3:30 PM, it was determined that the laboratory director failed to ensure that a quality control program was established and maintained to assure the quality of the melanoma testing it provided. Leica melanoma testing reagents were stored in a refrigerator where temperatures were not monitored per manufacturer instructions. See CFR 493.1252 (b), D tag D5413.