Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 12D0646259	**(X3) Date Survey Completed** 02/04/2022
Name of Provider or Supplier Hawaii Dept Of Health	**Street Address, City, State** 2725 Waimano Home Rd, Pearl City, 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**
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on mumps PCR test records review and laboratory personnel interviews on January 18, 2022, the laboratory failed to label mumps PCR test reagents with expiration dates. Findings included: a. In the Laboratory Preparedness and Response Branch (LPRB) - Biological Response Section (BRS) of the laboratory, it was the practice of the laboratory to perform patient testing using a mumps PCR test. b. Based on review of a patient mumps PCR test run performed by the laboratory on April 7, 2021, it was discovered that reagents, which included "Mumps Forward," "Mumps Reverse," "Mumps Probe," "HurRNase Forward," "HurRNase Reverse," "HurRNase Probe," "Human RNA Control - Stratagene," "Mumps Positive Control," and "Mumps Negative Control", used to perform the test run were not labeled with expiration dates. c. According to laboratory personnel, the laboratory tests less than 20 patient specimens annually using the laboratory's mumps PCR test.