Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0667110	08/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ken C Arakawa Md, Inc	1329 Lusitana St Ste 206, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing reporting records and an interview with the laboratory supervisor on 8/13/2019, it was determined that the laboratory failed to test chemistry samples it receives from the proficiency testing program in the same manner as it tests patient specimens. Findings include: 1. The laboratory participated in the American Proficiency Institute proficiency program for Chemistry in 2018 and 2019. In the first, second, and third proficiency testing events of 2018, and the first and second proficiency testing events of 2019, survey samples were tested twice, once by each of two testing personnel. Results reported to the proficiency testing program on the above events were a combination of results selected from the two individual testing personnel. For example in the 2018 first survey event, Testing Personnel A's results were reported for the following analytes from CH-01: Bilirubin Total, Calcium Total, Cholesterol HDL, Cholesterol Total, Creatine Kinase, Glucose, Cholesterol LDL, Triglycerides, Phosphorus, Uric Acid, Sodium, and Potassium. Testing Personnel B's results were reported for the following analytes from CH-01: ALT, AST, and Creatinine. 2. The laboratory supervisor stated during interview on 8/13/19, that patient samples for chemistry testing are performed and resulted by a single testing personnel. 3. The laboratory supervisor confirmed during interview on 8/13

	/19, that samples for chemistry Proficiency Testing during the listed events were not tested in the same manner as patient samples.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a 8/13/2019 review of laboratory maintenance records and an interview with the laboratory supervisor at 10:30 a.m., it was determined that the laboratory failed to perform and document weekly ACE Alera Wasserman maintenance activities. The findings include: 1. The ACE Clinical Chemistry Maintenance Log lists the following weekly tasks: 1) Inspect air filters, 2) clean exterior surfaces of the system, and 3) Clean reference housing. 2. Documentation of weekly maintenance performance was not available for review for: a. 2018: 2 of 4 weeks in February (2/5-2/10 and 2/19-2 /24), 1 of 4 weeks in March (3/26-3/31), 1 of 5 weeks in May (5/7-5/12), 1 of 4 weeks in June (6/11-6/16), 1 of 4 weeks in July (7/2-7/7), 1 of 4 weeks in October (10/8-10 /13), and 2 of 4 weeks in November (11/12-11/17 and 11/19-11/24) b. 2019: 1 of 4 weeks in February (2/11-2/16), 2 of 4 weeks in March (3/4-3/9 and 3/25-3/30), 1 of 4 weeks in April (4/8-4/13), 1 of 5 weeks in May (5/27-6/1), and 2 of 4 weeks in July (7 /1-7/6 and 7/22-7/27) 3. The laboratory supervisor stated that chemistry testing was performed on 35-40 patients per month.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing reporting records and an interview with the laboratory supervisor on 8/13/2019, it was determined that the laboratory director failed to ensure that chemistry samples it receives from the American Proficiency Institute proficiency testing program were tested in the same manner as it tests patient specimens. Refer to D2006.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on a 8/13/2019 review of laboratory maintenance records and an interview with the laboratory supervisor at 10:30 a.m., it was determined that the laboratory failed to ensure the establishment and maintenance of acceptable levels of analytical performance for its ACE Alera Wasserman chemistry testing . Refer to D5433.