Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D2079656	06/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kaloko Pain Center	75-184 Hualalai Rd Suite 302, Kailua Kona, 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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on an on-site inspenction and an interview with the laboratory testing personnel on 06/07/2019, the lab failed to establish for the Easy RA system the performance specifications for verification of positive results. Findings included: 1. The laboratory used the Medica Easy RA Chemistry Analyzer and LZI Enzyme Immunoassay to perform and report clinical laboratory test results on amphetamine, barbiturates, buprenorphine, cocaine metabolite, opiates, oxycodone, phencyclidine (PCP), and Ecstasy in patient specimens. FDA had not approved the use of both systems to be used together. 2. The package insert for the LZI Cocaine Metabolite Enzyme Immunoassay reagent by Lin-Zhi International Inc. May 2017 Rev.8 stated under Limitations that "positive results should be confirmed by other affirmative, analytical chemistry methods." 3. The package insert for the LZI Phencyclidine Enzyme Immunoassay reagent by Lin-Zhi International Inc. May 2017 Rev.9 stated under Limitations that "positive results should be confirmed by other affirmative, analytical chemistry methods." 4. The testing personnel verified that speciments with positive Easy RA results were not confirmed by other affirmatory analytical chemistry

	methods. 5. There were approximately 19,000 tests performed on the Medica Easy RA during 2018.