

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2079656	(X3) Date Survey Completed 12/17/2021
Name of Provider or Supplier Kaloko Pain Center	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and confirmation by the Technical Supervisor on 12/17/2021 at 2:30 PM, it was determined that the laboratory failed to enroll in a HHS approved proficiency testing (PT) program for the Toxicology testing it performed in 2021. The findings include: 1. The Technical Supervisor stated that the laboratory failed to renew its CAP Urine Drug Screen Testing Confirmation proficiency testing survey for 2021. 2. The laboratory performed 686,400 Thermo Fisher Scientific Indiko Plus drug tests and 5,720,000 Shimadzu 845 LCMS drug tests in 2021.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

This CONDITION is not met as evidenced by:

Based on a review of laboratory records and confirmation by the Technical Supervisor on 12/17/2021 at 2:30 PM, it was determined that the Laboratory Director failed to provide overall management and direction to ensure the laboratory was enrolled in an HHS approved proficiency testing (PT) program for the Toxicology testing it performed in 2021. See CFR 493.801, D tag D2000.