

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D2298142	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Iassay Hawaii	Street Address, City, State 75-5653 Kuakini Hwy, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the laboratory director on 12/11/2024 at 10:00 AM revealed the laboratory failed to follow its Competency Testing Program policy to assess the individual performing urine Fentanyl drug testing in 2024. The policy states "3. Competency testing will be performed on all technical staff on initial hire or assignment to perform the procedure, every six months during the initial year of employment, and annually thereafter". The laboratory performed an annual volume of 5 tests.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the laboratory director on 12/11/2024 at 10:00 AM revealed the laboratory failed to twice annually verify the accuracy of its qualitative urine Fentanyl drug testing in 2024. The laboratory performed an annual volume of 5 tests.</p>
D6095	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

The surveyor's review of laboratory records and an interview with the laboratory director on 12/11/2024 at 10:00 AM revealed the laboratory director failed to at least twice annually ensure the acceptable levels of its qualitative urine Fentanyl drug testing in 2024. See D tag D5217.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

The surveyor's review of laboratory records and an interview with the laboratory director on 12/11/2024 at 10:00 AM revealed the laboratory director failed to ensure that its Competency Testing Program policy for monitoring the individual performing urine Fentanyl drug testing was maintained in 2024. See D tag D5209.