

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0698804	(X3) Date Survey Completed 12/04/2023
Name of Provider or Supplier City & County Of Honolulu	Street Address, City, State 2226 Liliha St, Ste B1, 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
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: Based on a review of laboratory records and an interview with the technical consultant on 12/4/2023 at 9:30 AM. it was revealed that the laboratory failed to follow written policies and procedures to assess its testing personnel and technical consultant competency. The laboratory performed an annual volume of 1085 urine sediment examinations and 4195 urine specific gravity tests. The findings include: 1. Testing personnel #2 was hired in October 2022. Documentation of this individual's initial training and six month competency was not available for review. The 2023 annual competency assessment for urine sediment examinations and urine specific gravity tests did not follow CLIA's six procedures. 2. A competency assessment for the technical consultant based on CLIA responsibilities for this position was not performed in 2022 and 2023. This individual also performs testing on patient samples. The 2022 and 2023 annual competency assessment for urine sediment examinations and urine specific gravity tests did not follow CLIA's six procedures.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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</p>

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 review of laboratory maintenance records and an interview with the technical consultant on 12/4/2023 at 10:00 AM. it was revealed that the laboratory failed to perform annual preventive maintenance on its Nikon Eclipse E100LED MV microscope SN 731923 in 2021 and 2022. The laboratory performed an annual volume of 1085 urine sediment examinations.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and an interview with the technical consultant on 12/4/2023 at 9:30 AM. it was revealed that the laboratory director failed to ensure its quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: 1. The laboratory failed to perform annual preventive maintenance on its Nikon Eclipse E100LED MV microscope SN 731923 in 2021 and 2022. Refer to D tag D5433.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) 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:

Based on a review of laboratory records and an interview with the technical consultant on 12/4/2023 at 9:30 AM. it was revealed that the laboratory director failed to ensure its competency assessment program was maintained to assure the quality of laboratory services provided by its testing personnel. Refer to D tag D5209.