

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0698804	(X3) Date Survey Completed 02/25/2022
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory records and confirmation by the testing personnel on 02/25/2022 at 3:00 PM, it was determined that the laboratory failed to perform and document maintenance on its urine specific gravity refractometer as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: 1. ATAGO Quick Guide for urine specific gravity Pocket Pal-10S states the surface of the refractometer should be cleaned prior to Zero Set and UQC, and prior to and after each patient test. 2. ATAGO Quick Guide for urine specific gravity Pocket Pal-10S states the following "Instrument Cleaning & Precautions": a. Clean with Distilled Water (0.5 or 1L open expiry one month) b. Disinfect with 2% Chlorhexidine & 70% isopropyl alcohol prep pad or Caviwipes (Metrex). Use 2nd wipe to disinfect surface. Wipe dry. 3. Testing personnel stated that instrument cleaning and precautions were not performed on its ATAGO Pocket Pal-10S refractometer, SN B928931 in use since 10/17/2014. 4. The laboratory performed 6000 urine specific gravity tests in 2021.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:
Based on a review of laboratory records and confirmation by the testing personnel on 02/25/2022 at 3:00 PM, it was determined that the laboratory failed to perform and document function checks on its urine specific gravity refractometer as defined by the manufacturer and with at least the frequency specified by the manufacturer before patient testing is conducted. The findings include: 1. ATAGO Quick Guide for urine specific gravity Pocket Pal-10S states Zero Set must be "performed prior to quality control and patient testing". Use FORM A to record this activity. 2. ATAGO Quick Guide for urine specific gravity Pocket Pal-10S states "UQC is performed daily with patient use, weekly when not in use". Ensure "both QC levels are within documented range before proceeding with patient testing. Record all values on FORM A". 3. Testing personnel stated that instrument function checks were not performed on its ATAGO Pocket Pal-10S SN B928931 in use since 10/17/2014. Testing personnel also stated that a FORM A was not available for use in the laboratory. 4. The laboratory performed 6000 urine specific gravity tests in 2021.

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 review of laboratory records and confirmation by the testing personnel on 02/25/2022 at 3:30 PM, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for its ATAGO Pocket Pal-10S urine specific gravity refractometer test system. The findings include: 1. The laboratory failed to perform and document maintenance on its urine specific gravity refractometer as defined by the manufacturer and with at least the frequency specified by the manufacturer. See CFR 493.1254(a)(1), D tag D5429. 2. The laboratory failed to perform and document function checks on its urine specific gravity refractometer as defined by the manufacturer and with at least the frequency specified by the manufacturer before patient testing is conducted. See CFR 493.1254(a)(2), D tag D5431.