

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0933356	<b>(X3) Date Survey Completed</b>  09/03/2025
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Aquarium	<b>Street Address, City, State</b>  Centro Comercial Plaza Aquarium, Local 21, Toa Alta, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Aquarium on September 3, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on September 3, 2025.
<b>D5479</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(5)(g)</p> <p>(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.</p> <p>This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2024 - 2025), manufacturer's instructions and interview with the laboratory general supervisor on September 3, 2025 at 11:03 AM, it was determined that the laboratory did not follow manufacturer's instructions of the optimum temperature required to process urinalysis samples, when they processed and reported 7363 urinalysis patients tests from January 1, 2024 to September 3, 2025. The findings include: 1. The laboratory performs urinalysis tests with the Siemens Clinitek Advantus Analyzer. 2. On September 3, 2025 at 10:54 AM the manufacturer's instructions were reviewed, and it establishes on the environmental specifications that the optitimum operating temperature for urinalysis tests was from 22C to 26 C (72F to 79F). It also states that at temperatures under 22C (72F), urobilinogen and leukocyte results may be decreased, and at temperatures above 26C (79F), increased. 3. On September 3, 2025 at 10:58 AM, the quality control records for urinalysis tests were reviewed (years 2024 - 2025), and showed that the laboratory did not document the temperature when processing urinalysis samples from January 1, 2024 to September 3, 2025. 4. The laboratory general supervisor confirmed on September 3, 2025 at 11:03 AM, that the laboratory did not document the temperature</p>

when processing urinalysis samples, when 7363 patient specimens were processed and reported for urinalysis tests from January 1, 2024 to September 3, 2025.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on urinalysis quality control records review (years 2024 - 2025), manufacturer's instructions and interview with the laboratory general supervisor on September 3, 2025 at 11:03 AM.; it was determined that the laboratory director did not assure that the laboratory follows the manufacturer's instructions. Refer to D5479.

**D6148**

**GENERAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1463(a)(4)

(a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

This STANDARD is not met as evidenced by:

Based on urinalysis quality control records review (years 2024 - 2025), manufacturer's instructions and interview with the laboratory general supervisor (also testing personnel), on September 3, 2025 at 11:03 AM, it was determined that the laboratory general supervisor failed to monitor urinalysis test specimen examinations to ensure that acceptable levels of analytic performance are maintained for urinalysis tests. Refer to D5479.