

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2244393	(X3) Date Survey Completed 04/30/2026
Name of Provider or Supplier Athari Biosciences Inc	Street Address, City, State 45925 Horseshoe Drive, Suite 170, Sterling, VA	
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
D0000	An announced CLIA recertification survey was conducted at Athari BioSciences, Inc on April 30, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiency cited is as follows:
D5433	<p> MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) </p> <p> (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. </p> <p> This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, laboratory maintenance records, lack of documentation and an interview, the laboratory failed to establish and follow a policy to ensure pipette accuracy in calendar year 2025 for six (6) of six pipettes (timeframe of record review April 2024 until April 30, 2026). The findings include: 1. A review of the laboratory's policies and procedures revealed a procedure, "Virongy Biosciences SARS-CoV-2 Rapid Neutralizing Antibody Test", with a listing of single and multi-channel pipettes to be used in the procedure. 2. A review of the laboratory's maintenance records from April 1, 2024 until April 30, 2026 revealed calibration records for the 6 pipettes listed below: Rainin Single Channel Pipette XLS+ L-2 Serial # B939333159 Rainin Single Channel Pipette XLS+ L-20 Serial # B939331828 Rainin Single Channel Pipette XLS+ L-200 Serial # B939331797 Rainin Single Channel Pipette XLS+ L-1000 Serial # B939331697 Rainin 8 Channel Pipette Serial # B942422891 Rainin 8 Channel Pipette Serial # B942423275 Further review of the records revealed pipette calibrations were performed in April 2024 (calibration due April 2025) and February 2026 (calibration due February 2027). The pipette calibration records lacked documentation of pipette calibrations in 2025. The surveyor </p>

requested to review pipette calibrations for 2025. The laboratory provided no documentation for review. In an interview with the laboratory director on April 30, 2026, at 11:15 AM, the laboratory director stated, "The pipettes were not calibrated in 2025." 3. A review of the available laboratory policies and procedures revealed a lack of a policy for pipette accuracy checks. 4. In an interview with the laboratory director, technical supervisor and testing personnel on April 30, 2026 at 12:00 PM, the above findings were confirmed.