DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA VI 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov	04/23/2026, 04/27/2026
	FEI NUMBER 3020688999
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jen-Ting Chang, Lab Leader	
FIRM NAME Biosafety Testing Laboratory in Agricultural Technology Research Institute (ATRI)	STREET ADDRESS No.52, Kedong 2nd Rd.
CITY, STATE, ZIP CODE, COUNTRY Jhunan Township, Miaoli County 350401, Taiwan	TYPE ESTABLISHMENT INSPECTED Testing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to ensure that test materials conform to appropriate standards of identity, strength, quality and purity. Specifically,

Your test procedure WT-01-03, Mycoplasma Testing – (b) (4), Version 2.4, Effective 07/23/2023 allows for long-term storage of the (b) (4) unprocessed bulk (UPB) under frozen condition (Step (b) (4) for up to (b) (4) However, you were unable to provide supporting data to demonstrate that viability of *Mycoplasma spp.* in the (b) (4) can be maintained after (b) (4) of frozen storage. *Mycoplasma spp.* does not have cell walls and is prone to cell destruction during freezing and thawing absent the protection of its host cell. Long-term storage of the (b) (4) (b) (4) as permitted in WT-01-03 can potentially lead to false negative results and impact the safety of commercial (b) (4) product distributed to the United States market.

OBSERVATION 2

Not all laboratory records include accurate and complete data derived from all tests and examinations necessary to assure compliance with established specifications and standards. Specifically,

Your firm lacks an adequate audit procedure for digital microscopy images captured on each analyst's personal SD card, transferred to their work laptops, and uploaded to server for archival. On 04/23/2026, your Quality Director verbally confirmed that the quality unit does not review the original raw data stored on the SD cards to ensure all data reported is reliable and no data is omitted. Instead, the quality unit reviews images on the final report against archived images that do not represent the true copy of the original data. Microscopic images are used to support the final reportable result of USP <63> mycoplasma

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Charles Y. Kuo -S Digitally signed by Charles Y. Kuo -S Date: 2026.04.26 22:16:44 -04'00' YUN WU -S Digitally signed by YUN WU -S Date: 2026.04.26 22:15:26 -04'00'	Charles Kuo, Pharmaceutical Scientist Yun Wu, Pharmaceutical Scientist	April 27, 2026

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and USP <1237> *in vitro* virus testing of (b) (4) UPB.

OBSERVATION 3

Analytical assay invalidation and reanalysis are not always scientifically justified and documented under an appropriate system for quality review and trending. For example,

(b) (4) UPB sample of (b) (4) lot (b) (4), was tested on 12/11/2025 for (b) (4) (b) (4) by (b) (4) and the results were reanalyzed on 12/15/2025 because standard deviation (SD) for (b) (4) was (b) (4) Variation of (b) (4) is not among the system suitability criteria specified in WT-04-62, (b) (4) Assay, Version 1.3, Effective 06/23/2020 or the sample test record. (b) (4) represents the method limit of detection (LOD) at (b) (4) and the results are expected to have high variability. Nevertheless, you proceeded to re-analyze the data without obtaining prior approval from the quality unit and failed to initiate a deviation or laboratory investigation to document this event for future trending and continued improvement.

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	Charles Y. Kuo -S Digitally signed by Charles Y. Kuo -S Date: 2026.04.26 22:17:06 -04'00' YUN WU -S Digitally signed by YUN WU -S Date: 2026.04.26 22:15:58 -04'00'	Charles Kuo, Pharmaceutical Scientist Yun Wu, Pharmaceutical Scientist	April 27, 2026