DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	8/18/2025-8/29/2025* FEI NUMBER 3000204058

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sheryl J. Cyrus, Director, Operations II

FIRM NAME	STREET ADDRESS
Creative Testing Solutions	2424 W Erie Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tempe, AZ 85282-3113	Testing Laboratory

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

Testing for communicable disease agents was not performed in accordance with the manufacturer's instructions.

Specifically,

During testing of HCT/P donors for relevant communicable disease agents and diseases (RCDADs), you failed to follow the manufacturer's instructions. In the (b) (4), you utilize (b) (4) reservoir to store reagents briefly during confirmatory testing to allow technicians to utilize a (b) (4). The manufacturer's instructions state to use (b) (4) reservoir, not (b) (4) reservoir.

Your technicians utilized (b) (4) reagent reservoirs in the testing of the following tests:

1. Bio-Rad HIV-1/HIV-2 PLUS O EIA
2. Bio-Rad GS HBsAg EIA
3. Avioq HTLV-1/II

In addition to utilizing (b) (4), you are cleaning the (b) (4) reagent reservoir using an unvalidated cleaning process that is required by the manufacturer to reuse the reservoir. Per your firm's representatives, these reagent reservoirs are washed using (b) (4) but no standard operating procedure has been established and no record of cleaning have been documented.

From 07/15/2023 to present, you have performed (b) (4) HIV-1/HIV-2 Plus O EIA, (b) (4) GS HBsAg,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily S Mcgann, Investigator William F Lagud, Investigator X William F Lagud Investigator Signed By: William F. Lagud Jr -S Date Signed: 08-29-2025 14:27:17	8/29/2025

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and (b) (4) HTLV-I/II

OBSERVATION 2

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically,

A. None of your firm's standard operating procedures require investigation into all unexplained discrepancies. Your SOP titled, *Error Management*, only requires investigation into customer complaints and errors involving released test results.

B. Your firm failed to thoroughly investigate and document improper quality control (QC) lots being maintained for reference ranges on the (b) (4) instrument. During review of donor serum protein electrophoresis results, I observed that incorrect reference percentages were used for instrument QC due to the incorrect lot number being recorded. Further review of records determined that this QC lot error was documented at least three times, on 05/15/2024, 05/16/2024, and 05/17/2024. A handwritten note dated 06/02/24 was included in batch records from 05/15/2024, 05/16/2024 and 05/17/2024. This documentation did not include when the issue was discovered, how many daily QCs were affected by this error, follow-up actions, who was involved in review, and what was considered for acceptance of released affected test results.

***DATES OF INSPECTION**

8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed), 8/28/2025(Thu), 8/29/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily S Mcgann, Investigator William F Lagud, Investigator	X William F Lagud Investigator Signed By: William F. Lagud Jr -S Date Signed: 08-29-2025 14:27:17	8/29/2025

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X Emily S Mcgann
Investigator
Signed By: Emily S. Mcgann -S
Date Signed: 08-29-2025 14:28:07

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Emily S Mcgann, Investigator
William F Lagud, Investigator

X William F Lagud
Investigator
Signed By: William F. Lagud Jr -S
Date Signed: 08-29-2025 14:27:17

DATE ISSUED
8/29/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."