DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	3/9/2026-3/12/2026
	FEI NUMBER 3003261962

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Crystal Carnes, Vice President

FIRM NAME	STREET ADDRESS
Custom Analytics LLC	3789 Thomas Sumter Hwy
CITY, STATE, ZIP CODE, COUNTRY Dalzell, SC 29040-9056	TYPE ESTABLISHMENT INSPECTED Contract Analytical 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 I OBSERVED:

OBSERVATION 1

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically,

Your laboratory has three problems that could contaminate testing:

1. The pass-through counter has no physical barrier, allowing contaminants to enter the lab from the office area.
2. A dog was seen in the office next to the lab. This violates your own procedure (SOP CA26150, Section 12.5), which prohibits animals in laboratory areas. Animal hair, dander, and microorganisms can easily move into the lab through the open pass-through.
3. The lab door opens straight to the outdoor environment, allowing airborne particles and contaminants to enter. The lab tests drug products, including OTC (b) (4) (Lot # (b) (4)) and (b) (4) (Lot # (b) (4) . These uncontrolled environmental exposures could compromise your microbiological media preparation and test results.

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	J'Maica J Hunter, Investigator X J'Maica J Hunter Investigator Signed By: 1001056020 Date Signed: 03-12-2026 17:13:22	3/12/2026

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Specifically,

Your procedure SOP CA26150 – Cleaning and Maintenance of Laboratory and Laboratory Equipment, Section 10.2, states that a (b) (4) cleaning of laboratory floors is to be performed (b) (4)

However, during the inspection your Vice President stated that your firm does not maintain records documenting completion of the (b) (4) (b) (4) cleaning of laboratory floors because the procedure does not require maintaining a log.

Your firm could not demonstrate that the required (b) (4) (b) (4) cleaning of laboratory floors is performed.

Failure to verify sanitation activities may allow accumulation of environmental contaminants within the laboratory environment, which may affect laboratory operations including microbiological testing and media preparation performed by your laboratory.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm initiated Corrective and Preventive Action (CAPA) 501-01-2026 on January 15, 2026, after inconsistent results were observed during (b) (4) balance performance qualification testing of laboratory balances.

The investigation concluded that SOP CA501 – Laboratory Balance OQ and PQ Procedures incorrectly implemented the repeatability requirements of USP <41>.

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However, the investigation documentation did not include a documented root cause determination.

Additionally, your procedure SOP CA506 – Corrective and Preventative Action Plans and Deviations, Section 6.4, requires investigation reports to include identification of the root cause. The investigation documentation did not include a documented root cause determination.

The CAPA report states that SOP CA501 was updated and staff were retrained, but does not include documentation of a scientifically justified root cause analysis or evaluation of the potential impact to previously generated laboratory data.

Your firm documented the investigation as completed on January 27, 2026.

Additionally, the investigation did not include a documented assessment to determine whether previously generated laboratory data may have been affected by the use of the incorrect procedure.

Failure to adequately investigate discrepancies and determine root cause may affect the reliability of laboratory data generated using the procedure.

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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."