DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	7/21/2025-7/24/2025
	FEI NUMBER 3001451800

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. OBrien, Chief Operating Officer

FIRM NAME	STREET ADDRESS
C.G. Laboratories, Inc.	1410 Southtown Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Granbury, TX 76048-2663	HCT/Ps 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

Corrective actions relating to core CGTP requirements did not include both short term corrective actions to address the immediate deficiency and long term corrective actions to prevent recurrence.

Specifically, Your firm did not initiate nor implement any corrective actions under the Corrective Action Request form ((b) (4)).

Your quality assurance personnel failed to verify that all preventive maintenance documents were properly (b) (4) into your (b) (4) storage system before (b) (4) . Thus, preventative maintenance records for the year (b) (4) were not retained. There was no corrective action performed in response to the loss of the records and no preventive action was included.

You tested a total of (b) (4) tissue samples for Bioburden and (b) (4) tissue samples for Sterility from (b) (4) .

OBSERVATION 2

Records were not retained for the appropriate length of time, 10 years after their creation.

Specifically, You failed to retain the preventive maintenance records for the year (b) (4).

On 07/21/2025, You were unable to provide the (b) (4) (b) (4) preventive maintenance records for the Autoclaves ((b) (4) used to sterilize laboratory (b) (4) (b) (4), and (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ramon L Gonzalez-Prieto, Investigator Michelle Paxon, Investigator	X Ramon L Gonzalez-Prieto Investigator Signed By: RAMON L GONZALEZ-PRIETO -S Date Signed: 07-24-2025 10:06:26	7/24/2025

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On 07/22/2025 you were unable to provide the (b) (4) (b) (4) preventive maintenance records for the (b) (4) ((b) (4)) used for sterility testing of tissue samples and the microbial air sampler equipment ((b) (4)).

According to your Standard Operational Procedure titled, "Quality Records" on page 2 it states the following: "Customer Records/Manufacturing Records are stored for a 10-year minimum period."

You destroyed the (b) (4) preventative maintenance records. You tested a total of (b) (4) tissue samples for Bioburden and (b) (4) tissue samples for Sterility from 2023-2025.

OBSERVATION 3
Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not established.

Specifically, Your firm did not establish a standardized operational procedure (SOP) on how to perform preventative maintenance on the (b) (4) ((b) (4)).

According to the Manufacturer's (b) (4) Operation Manual, " (b) (4) on (b) (4) the (b) (4) should be replaced every (b) (4) to (b) (4) days, depending upon the amount of (b) (4) in the (b) (4) and (b) (4) filters will normally require replacing (b) (4) ."

You have been in possession of (b) (4) since (b) (4) ; (b) (4) is still currently in-use. You tested a total of (b) (4) tissue samples for Bioburden and (b) (4) tissue samples for Sterility from (b) (4) .

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X Michelle Paxon
Investigator
Signed By: 2003998263
Date Signed: 07-24-2025 10:07:17

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Ramon L Gonzalez-Prieto, Investigator
Michelle Paxon, Investigator

X Ramon L Gonzalez-Prieto
Investigator
Signed By: RAMON L GONZALEZ-PRIETO -S
Date Signed: 07-24-2025 10:06:26

DATE ISSUED
7/24/2025

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."