

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 3/23/2026-3/24/2026 FEI NUMBER 3013952826			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Haydee I. Romandia, Customer Service Specialist & Quality Assurance Manager					
FIRM NAME Cantor BioConnect, Inc.		STREET ADDRESS 9456 Cuyamaca St Ste 101			
CITY, STATE, ZIP CODE, COUNTRY Santee, CA 92071-5919		TYPE ESTABLISHMENT INSPECTED Blood Component Storage and Distribution 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 Failure to establish and maintain procedures for obtaining information on all complaints for a distributed biological product subject to biological product deviation reporting. Specifically, your firm has not adequately established and maintained procedures for a complaint handling system for obtaining information on all complaints for distributed biological products to ensure that complaints are consistently categorized or coded, investigated for root cause analysis, corrective action, and verification of effectiveness to prevent recurrence. For example, your firm documented three (3) consumer complaints from March 2024 to March 2026. One (1) out of three (3) consumer complaints (NCR (b) (4)) utilized (b) (4) to determine Root Cause Analysis (RCA); however, the other two (2) consumer complaints (NCR (b) (4)) fail to document the use of (b) (4) to determine RCA. Also, your consumer complaint records fail to consistently document containment activities and/or corrective action(s) and effectiveness measurements.					
OBSERVATION 2 Equipment used in the storage and distribution of blood and blood components is not standardized on a (b) (4) as prescribed in the SOP Manual. Specifically, your firm has (b) (4) -20°C freezers used for storage of biological products that are in part intended for further manufacturing into in vitro diagnostic use such as Human Serum. Preventive					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Creighton T Tuzon, Investigator James A Banks, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 3/24/2026 Creighton T Tuzon Investigator Signed By: Creighton Tuzon -G Date Signed: 03-24-2026 13:43:02 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Creighton T Tuzon, Investigator James A Banks, Investigator	DATE ISSUED 3/24/2026 Creighton T Tuzon Investigator Signed By: Creighton Tuzon -G Date Signed: 03-24-2026 13:43:02
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Haydee I. Romandia, Customer Service Specialist & Quality Assurance Manager

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maintenance for (b) (4) of your firm's -20°C freezers (Equipment ID (b) (4)) were not conducted according the manufacturer specification since implementing the use of these (b) (4) -20°C freezers in October 2021. Instead of conducting preventive maintenance (b) (4) as specified in the manufacturer's manual, your firm implemented (b) (4) preventive maintenance for these (b) (4) 20°C freezers beginning in September 2025.

X James A Banks
Investigator
Signed By: 2004835222
Date Signed: 03-24-2026 13:43:47

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Creighton T Tuzon, Investigator James A Banks, Investigator	Creighton T Tuzon Investigator Signed By: Creighton Tuzon -G Date Signed: 03-24-2026 13:43:02 X	DATE ISSUED 3/24/2026

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."