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	4/21/2025-4/30/2025* FEI NUMBER 3015252551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Victor J. Maines, VP of Sales and Marketing

FIRM NAME	STREET ADDRESS
Invitrx Therapeutics Inc.	20503 Crescent Bay Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Forest, CA 92630-8825	HCT/P Manufacturer

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

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically, from [redacted], human [redacted] blood received by your firm were not evaluated or documented for donor eligibility. We reviewed a total of [redacted] products received by your firm and processed, do not have any accompanying donor eligibility documents.

OBSERVATION 2

A responsible person did not document and date the determination that an HCT/P is available for [redacted].

Specifically, you failed to ensure that approximately [redacted] human [redacted] blood units, received and processed between [redacted], were released by a qualified responsible person [redacted] products without documented release increases the risk of releasing products that may not meet established safety, quality, and regulatory requirements.

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 has processed and stored approximately [redacted] human [redacted] blood products, between [redacted] without establishing and maintaining written procedures

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Creighton T Tuzon, Investigator Laurissa S Flowers, Investigator	X Creighton T Tuzon Investigator Signed By: Creighton Tuzon -S Date Signed: 04-30-2025 09:41:23	4/30/2025

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covering critical aspects of manufacturing. Specifically, you have not established procedures for, but not limited to:

1. Verification of supplies and reagents,
2. Processing and processing controls,
3. (b)(4) controls,
4. Storage conditions, and
5. Receipt, (b)(4), and (b)(4) activities, including product (b)(4) and (b)(4) conditions.

Additionally, you have no written procedures for all steps in the manufacture of human (b)(4) blood intended for (b)(4). This includes, but is not limited to, procedures addressing facility management, environmental controls, equipment maintenance and cleaning, supply and reagent verification, and processing controls.

Between (b)(4), you processed and stored approximately (b)(4) of human (b)(4) blood without documented manufacturing procedures.

OBSERVATION 4

Storage areas and stock rooms were not controlled to prevent HCT/Ps from improperly being made available for (b)(4).

Specifically, your current inventory system does not adequately support the retrieval of product for review or (b)(4). All freezer storage units contain product that is potentially available for (b)(4); however, much of this product is expired. Furthermore, there is no clear designation of product status, specifically, no product is (b)(4) as quarantined or for (b)(4)

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use only. This lack of segregation and labeling poses a risk of (b)(4) non-compliant or unsuitable product.

OBSERVATION 5

The records management system did not maintain records to facilitate review of particular HCT/Ps history subsequent to release as part of a follow-up evaluation or investigation.

Specifically, you failed to maintain processing records in an organized and controlled system. This includes, but is not limited to, records related to processing, sterility testing, equipment logs, facility maintenance, supply and reagent usage, and product labeling. The lack of an organized records management system compromises the ability to ensure the accuracy, traceability, and integrity of manufacturing and quality activities.

OBSERVATION 6

Donors were not screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases.

Specifically,

a. You failed to screen donors of human (b)(4) blood intended for (b)(4) to physicians for risk factors or clinical evidence of communicable disease agents. We reviewed a total of [redacted] (b)(4) products received by your firm and processed to not have any accompanying donor eligibility documents.

b. You failed to screen donors of human (b)(4) blood intended for (b)(4) or for (b)(4) for risk factors or clinical evidence of communicable disease agents. From (b)(4), you collected approximately (b)(4) of human (b)(4) without documented donor screening.

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OBSERVATION 7

A quality program which addresses all of the core CGTP requirements, appropriate for the HCT/Ps manufactured and the manufacturing steps performed, has not been established.

Specifically, you failed to establish and maintain a quality program intended to prevent the introduction, transmission, or spread of communicable disease during the manufacturing of human (b)(4) blood.

OBSERVATION 8

A method has not been established in the tracking system to document the disposition of each HCT/P.

Specifically, you have not established a tracking system for incoming human (b)(4) blood products. During review of your (b)(4) of human (b)(4) blood products, no lot number was recorded and/or no record of the (b)(4) was made.

OBSERVATION 9

Equipment used for manufacturing HCT/Ps was not cleaned, sanitized and maintained according to established schedules.

Specifically,

a. You failed to perform and document maintenance, including quality control (QC) checks and cleaning, for the general (b)(4) after February 8, 2022. No maintenance activities were recorded from February 2022 through March 2025. Failure to maintain critical equipment may impact the accuracy and reliability of analytical testing results.

b. You failed to conduct routine maintenance for (b)(4) from September 2022 through March 2025. (b)(4) is used in the processing of human (b)(4) blood and (b)(4)

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tissue. The lack of maintenance in a classified (b)(4) environment increases the risk of contamination and compromises product integrity.

***DATES OF INSPECTION**

4/21/2025(Mon), 4/22/2025(Tue), 4/23/2025(Wed), 4/24/2025(Thu), 4/25/2025(Fri), 4/28/2025(Mon), 4/29/2025(Tue), 4/30/2025(Wed)

X Laurissa S Flowers
Investigator
Signed By: LAURISSA S. FLOWERS -S
Date Signed: 04-30-2025 09:42:09

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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."