DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	9/8/2025-9/12/2025
	FEI NUMBER 3027286748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jennifer A. Sawkins, Vice President of Operations

FIRM NAME	STREET ADDRESS
Donor Services Laboratories Inc Tampa	1410 N 21st St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tampa, FL 33605-5313	Tissue 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

Records were not maintained concurrently with the performance of each step.

Specifically, incubation times for the (b) (4) are not concurrently documented. On 9/9/2025, technologist (b) (5), (b) (7)(C) was observed recording the incubation stop time (b) (4) the (b) (4) of incubation. When questioned, the technologist stated that the time recorded represented the (b) (4) rather than the (b) (4) the plate (b) (4) from the incubator. A second technologist, (b) (5), (b) (7)(C) confirmed that they were trained to document (b) (4) (b) (4). This practice does not ensure accurate and contemporaneous recording of incubation stop times.

OBSERVATION 2

The quality program does not include the investigation and the documentation of HCT/P deviations relating to core CTGP requirements.

Specifically, approximately 21 failed test runs from June 2024 to present were reviewed and 18 appeared to be lacking details specific to the investigation, outcome, and actions taken. For example:

a) (b) (4) Failed Run Report dated 4/5/2025 documents that the cause of fail is (b) (4) (b) (4)

b) (b) (4) Failed Run Report dated 2/3/2025 documents that the cause of fail is (b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Steen N Graham, Investigator
Nerming V Briones, Investigator
Lura D Kelly, Investigator

X Nerming V Briones Investigator Signed By: Nerming Briones -S Date Signed: 09-12-2025 14:46:04

DATE ISSUED
9/12/2025

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(b) (4).

c) (b) (4) Failed Run Report dated 6/14/2024 documents that the cause of fail is (b) (4).

d) (b) (4) Failed Run Report dated 6/19/2024 documents that the cause of fail is (b) (4).

Additionally, your firm was not able to provide failed test run investigations from June 2023 to May 2024.

OBSERVATION 3

Records did not identify the person performing the work and were not detailed as necessary to provide a complete history of work performed.

Specifically, your batch checklist forms of various test records were missing information. For example:

a) (b) (4), dated 9/1/2024, did not contain the plate reading time and time out and time in information for the test kit.

b) (b) (4), dated 9/1/2024, did not contain the batch number, initial and date of the technologist performing the work, and time out and time in for the test kit.

c) (b) (4), dated 9/1/2024, did not contain the technologist who performed the (b) (4) and time out and time in for the test kit.

d) (b) (4), dated 9/9/2025, did not contain the stop time after incubating the samples.

e) (b) (4), dated

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2/14/2025, did not contain the time the (b) (4) was added.

f) (b) (4) dated 2/14/2025, did not contain the time in information for the test kit.

g) (b) (4) dated 2/14/2025, did not contain the time the (b) (4) (b) (4) was added.

Additionally, when we reviewed the read time print out, no time zone is indicated. The (b) (4) (b) (4) explained that the read time print outs use (b) (4) and not (b) (4) (b) (4). For example, the read out for Batch (b) (4) displayed a printed on date of (b) (4).

X Lura D Kelly
Investigator
Signed By: 2001857765
Date Signed: 09-12-2025 14:46:50

X Steen N Graham
Investigator
Signed By: Steen N. Graham -S
Date Signed: 09-12-2025 14:47:34

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."