DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809	9/11/2019-9/18/2019* FEI NUMBER 3015767533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Margarita Gil De Rubio, Medical Technologist

FIRM NAME	STREET ADDRESS
Laboratorio Banco Vida	Upr Comprehensive Cancer Center Grounds Of Medical Center
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Juan, PR 00935-0001	Human Tissue Establishment

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

Environmental conditions existed in which contamination or cross contamination of HCT/Ps or equipment could occur, and environmental conditions were not adequately controlled and proper conditions for operations were not provided.

Specifically,

1) There are no environmental control procedures established by your firm.

2) There are no environmental monitoring for your Biological Safety Cabinet (BSC) is performed at your firm. Your BSC is used for processing/manufacturing umbilical cord blood tissues for autologous, first and second-degree blood relatives use.

3) On 09/16/19, autologous umbilical cord blood batches (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) were processed alternating the use of the BSC during processing of allogeneic umbilical cord blood tissue in (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) that was processed by another firm. There are no procedures in place for processing multiple donor umbilical cord blood to assure that cross contamination does not occur.
3) On 09/16/19, we observed only the (b) (4) of the (b) (4) of the BSC being wiped with (b) (4) between switching manufacturing processes for the batches (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C).
4) On 09/16/19, we observed the processing of two autologous umbilical cord blood (UCB) batches (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C). We observed the Medical Technologist bringing (b) (4) and (b) (4) that were not disinfected into the BSC during processing.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator Annette Melendez, Investigator	X Irina Gaberman Investigator Signed By: Irina P. Gaberman -S3 Date Signed: 10-22-2019 13:37:27	10/22/2019

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OBSERVATION 2

Processes with results which could not be fully verified by inspection and tests, were not validated and approved according to established procedures.

Specifically,

The aseptic process used to manufacture umbilical cord blood (UCB) tissues was not validated for autologous and first and second degree relatives. There were (b) (4) UCBs manufactured in 2018 and (b) (4) in 2019. One processed UCB batch (b) (4), (b) (6), (b) (7)(C) collected on (b) (6), (b) (7)(C) was released for transplantation to a first degree relative on (b) (6), (b) (7)(C).

OBSERVATION 3

Records were not detailed as necessary to provide a complete history of work performed.

Specifically,

Specifically, the aseptic processing steps described in your standard operating procedure BV 511 (HPC-C Manufacturing) are not documented during manufacturing of autologous and first and second degree relatives UCBs to assure all steps were performed as directed, including (b) (4) (b) (4) steps were followed.

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OBSERVATION 4

Facilities were not of suitable size and construction to prevent contamination of HCT/Ps with communicable disease agents and ensure the orderly handling of HCT/Ps without mix-ups.

Specifically,

On 09/16/19, autologous umbilical cord blood batches (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) were processed alternating the use of the Biological Safety Cabinet during processing of allogeneic umbilical cord blood tissue in (b) (4), (b) (6), (b) (7)(C) that was processed by another firm. We observed only the (b) (4) of the (b) (4) of the BSC being wiped with (b) (4) between switching manufacturing processes for the batches.

OBSERVATION 5

Environmental conditions were not monitored for microorganisms.

Specifically,

There are no written environmental control procedures established at your firm.

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OBSERVATION 6

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

Specifically,

Specifically, the following units had post processing samples that were positive for micro, but you did not conduct an investigation to determine the cause of the positive result: (b) (4), (b) (6), (b) (7)(C) collection date (b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C) collection date (b) (6), (b) (7)(C).

*DATES OF INSPECTION

9/11/2019(Wed), 9/12/2019(Thu), 9/13/2019(Fri), 9/16/2019(Mon), 9/17/2019(Tue), 9/18/2019(Wed)

X Annette Melendez S

Digitally signed by Annette Melendez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19300300.100.1.1=35098, cn=Annette Melendez -S
Date: 2019.10.22 13:58:40 -04'00'

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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."