DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	4/7/2026-4/29/2026* FEI NUMBER 1000100754

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bradley P. Glover, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Berkeley Biologics LLC	880 Harbour Way S Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richmond, CA 94804-3650	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

Donors were not determined to be ineligible that had risk factors or clinical evidence of communicable disease agents.

This is a repeat observation.

Your firm failed to determine as ineligible HCT/P donors with a documented diagnosis or clinical evidence of (b) (6), (b) (7)(C) in their available medical records during the hospital stay immediately preceding (b) (6), (b) (7)(C) Specifically,

A. Donors previously identified during the FDA inspection conducted 09/05-25/2023 as having risk factors for (b) (6), (b) (7)(C) were not determined ineligible; despite an evaluation by an independent infectious disease specialist determining the donor ineligible. Specifically, (b) (4) donors were re-screened by an independent infectious disease specialist, (b) (4) of these were determined to be ineligible due to (b) (6), (b) (7)(C) risk factors. Yet, (b) (4) of the (b) (4) were ultimately determined eligible by your firm. For example,

1. Your firm was previously cited because during the previous inspection, medical records from Donor (b) (6), (b) (7)(C) hospital stay immediately preceding (b) (6), (b) (7)(C) revealed documented medical diagnoses of (b) (6), (b) (7)(C) Despite these risk factors for communicable disease, your firm initially determined the donor eligible on 02/15/2022.

   Following the FDA inspection, your firm re-evaluated Donor (b) (6), (b) (7)(C) On 6/26/2025, an independent infectious disease specialist determined the donor ineligible due to (b) (6), (b) (7)(C) risk factors, including the documented diagnoses of (b) (6), (b) (7)(C)

AMENDMENT 1

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	Shelley H Beausoleil, Investigator Conor J Mccarron, Investigator	X Shelley H Beausoleil Investigator Signed By: SHELLEY H. BEAUSOLEIL, S Date Signed: 05-07-2026 12:46:31	5/7/2026

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(b) (6), (b) (7)(C) However, on 6/28/2025, your firm's contracted medical director determined the donor eligible.
Your contracted medical director did not make any changes to the steps he previously used to screen these donors for (b) (6), (b) (7)(C)
At the time of this second eligibility determination, in-date products from this donor remained in distribution.
Other examples include Donor ID Numbers: (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
At least (b) (4) allografts from these (b) (4) donors have been distributed.

B. Your firm continues to accept donors who should have been determined ineligible due to risk factors for (b) (6), (b) (7)(C) For example,

1. The medical records for the hospital stay immediately preceding Donor (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) indicated a medical diagnosis of (b) (6), (b) (7)(C) as well as clinical signs of (b) (6), (b) (7)(C) This donor was determined eligible by your contracted medical director on February 18, 2026. Your firm received (b) (6), (b) (7)(C) from this donor.

2. The medical records for the hospital stay immediately preceding Donor (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) indicated there was clinical evidence and a diagnosis of (b) (6), (b) (7)(C) documented in the medical records including specific mention of (b) (6), (b) (7)(C) secondary to (b) (6), (b) (7)(C) due to (b) (6), (b) (7)(C) and the following clinical evidence including evidence of more severe signs of (b) (6), (b) (7)(C)

   Donor (b) (6), (b) (7)(C) was determined eligible by your contracted medical director on February 26, 2026.

OBSERVATION 2

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You did not ensure that establishment(s) that by contract, agreement or arrangement, perform manufacturing steps for you were in compliance with applicable CGTP requirements after information became available that suggested the establishment was no longer in compliance.

This is a repeat observation.

Specifically, your quality program did not ensure that all responsible people adequately screen donors in accordance with regulatory requirements.

B. Donors are being determined eligible if it is concluded that the donor was not (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) rather than evaluating whether the donor had (b) (6), (b) (7)(C) risk factors during the hospital stay immediately preceding (b) (6), (b) (7)(C) For example,

1. On (b) (6), (b) (7)(C) your firm's contracted medical director screened Donor (b) (6), (b) (7)(C) The medical director failed to consider all required clinical evidence during the eligibility determination. Specifically, the medical director did not consider the documented medical diagnosis of (b) (6), (b) (7)(C) during the hospital stay immediately preceding (b) (6), (b) (7)(C) Instead, the evaluation only considered whether evidence of (b) (6), (b) (7)(C) was present (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)

2. On (b) (6), (b) (7)(C) your firm's contracted medical director screened Donor (b) (6), (b) (7)(C) This donor was screened for active (b) (6), (b) (7)(C) at (b) (6), (b) (7)(C) In this case, this decision was made because it was not mentioned in the discharge summary. This donor was determined to be eligible on February 18, 2026.

C. (b) (6), (b) (7)(C) blood cultures are inappropriately used to rule out systemic infection. For example, on (b) (6), (b) (7)(C) your firm's contracted medical director screened Donor (b) (6), (b) (7)(C) and records showed a (b) (6), (b) (7)(C) was ruled out because the blood cultures were (b) (6), (b) (7)(C) This donor had a medical diagnosis of (b) (6), (b) (7)(C) yet was determined eligible on February 18, 2026, by the medical director.

D. Your firm did not ensure that contracted consultants hired specifically to perform re-screening of

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donors with risk factors for (b) (6), (b) (7)(C) received adequate training. For example, on June 26, 2025, available medical records for Donor (b) (6), (b) (7)(C) were reviewed. The records demonstrated that contracted consultants were trained to interpret (b) (6), (b) (7)(C) blood cultures as confirmation that (b) (6), (b) (7)(C) had resolved (b) (6), (b) (7)(C) which is an approach that does not adequately address (b) (6), (b) (7)(C) risk factors in accordance with regulatory requirements.

E. Your firm has not ensured all your recovery partners comply with CGTP requirements for donor screening. For example, your recovery establishment reviewed the medical records for donor (b) (6), (b) (7)(C) and notified you that their review of the donor's hospital records from the hospital stay immediately preceding (b) (6), (b) (7)(C) were noted to have (b) (6), (b) (7)(C) in the admission records. Despite their knowledge of this documented evidence of (b) (6), (b) (7)(C) your recovery partner did not reject the donor. This donor's tissue was sent to your firm on (b) (6), (b) (7)(C) Your signed agreement with this recovery partner establishes that they are responsible for recovering (b) (6), (b) (7)(C) tissue in accordance with all applicable regulatory standards.

OBSERVATION 3

Investigation of deviations related to core CGTP requirements did not include a review and evaluation of the deviation, efforts to determine the cause of the deviation and corrective action(s) to address the deviation and prevent recurrence.

Specifically, your firm did not thoroughly investigate deviations related to core CGTP requirements. For example,

A. Your firm did not take corrective and preventive actions after identifying that changes to your recovery partner(s)' donor screening process were the root cause for deviations involving screening donors for (b) (6), (b) (7)(C)

B. Your firm did not consider all four criteria necessary to meet the definition of an HCT/P when re-evaluating product lines. Corrective action was limited to reviewing and taking actions on

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only those product lines where bone and cartilage were combined.

C. You did not identify instances when your recovery partners did not adequately screen donors in accordance with regulatory requirements as deviations. As a result, these instances were not investigated, a root cause was not established, and corrective and preventative actions were not considered. For example, your recovery partner didn't screen Donor ID # (b) (6), (b) (7)(C) in accordance with regulations, nor did you investigate it or take corrective actions.

D. Your firm did not adequately investigate Complaint # 2025-0001. You failed to identify that Donor # (b) (6), (b) (7)(C) was not adequately screened for (b) (6), (b) (7)(C) In addition, this donor was screened (b) (6), (b) (7)(C) the initiation of your CAPA 0004 and CAPA 0005, but you failed to include this donor in your investigation of these CAPAs. Consequently, the donor was not re-evaluated by your independent infectious disease specialist.

OBSERVATION 4

Procedures were not designed to ensure compliance with the donor eligibility requirements.

Specifically, your firm's donor screening procedures are not designed to ensure donors with risk factors for a relevant communicable disease are determined ineligible. The following are meant to be examples, and these do not constitute an all-inclusive list.

A. SOP-0006 (Donor Eligibility Screening Criteria), inappropriately allows donors with a documented history of (b) (6), (b) (7)(C) to be determined eligible if it is concluded that the (b) (6), (b) (7)(C) had resolved (b) (6), (b) (7)(C)

B. Your procedures do not identify the actions your firm must take when positive blood cultures are found in the available medical records.

C. Your procedures are not designed to ensure donors with physical evidence of syphilis and nonmedical percutaneous drug use such as needle tracks including results of your examination of tattoos, which might be covering needle tracks are determined ineligible. For example, your firm established an arrangement with agencies that perform tissue recovery to also perform the physical examination. Your firm's procedures do not establish which records must be reviewed

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prior to making an eligibility determination and the acceptability of the physical examination records, when those are prepared by another establishment.

D. Your procedures don't include which records must be reviewed when screening for each RCDAD. For example, you have not established steps covering which donor screening question from the Donor Risk Assessment Interview (DRAI) must be reviewed and which relevant information must be found in that record.

OBSERVATION 5

Supplies and reagents were used before they were verified to meet specifications designed to prevent the introduction, transmission, or spread of communicable disease.

Specifically, your firm failed to verify that your (b) (4) was qualified for use in HCT/P manufacturing. On 04/13/2026, we observed that (b) (4) Lot # (b) (4) was stored in refrigerator (b) (4) and had been released for manufacturing use on (b) (4) The label and Certificate of Analysis both identified this reagent as "For Research Use Only." Your firm uses this solution as a component during your lyophilization and (b) (4) processing steps and is present in your lyophilized birth tissue products and hydrated dermis products.

OBSERVATION 6

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, your firm failed to adequately control environmental conditions.
Alarm monitoring review was not conducted when environmental controls exceeded your established set points. Action level alarms within your Building Management System (BMS) were not designated as critical or non-critical as required by your procedure SOP-0069 "Building Management System," dated

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17 Feb 2025, Revision 05. For example,

A. Temperature Action Alarms in Room (b) (4) were not acted upon on the following dates: (b) (4) On each occasion, the temperature was recorded (b) (4) your set action level of (b) (4) in your (b) (4) This room is used for tissue processing and houses your (b) (4) (b) (4) Your (b) (4) manual states: (b) (4) (b) (4)

B. Your facility is not monitoring relative humidity within your tissue processing space as environmental control. (b) (4) manual states that the machine must operate between (b) (4) humidity.

***DATES OF INSPECTION**

4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/29/2026(Wed)

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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."