DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	1/6/2026-1/15/2026* FEI NUMBER 3000215347

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jennifer K. Prinz, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Donor Alliance, Inc.	200 Spruce St Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80230-7127	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 screened by a review of relevant medical records for of communicable disease agents and diseases.

Specifically, your firm did not adequately screen Donor ID # (b) (4), (b) (6), (b) (7)(C). Your firm determined the donor to be suitable when the donor should have been determined unsuitable. The donor medical records documented a medical diagnosis of sepsis and two or more clinical signs and symptoms of a systemic infection. This donation was sent to one of your processors and subsequently transplanted.

OBSERVATION 2

Adverse reactions involving a communicable disease related to HCT/Ps were not investigated.

Specifically, adverse reactions are not adequately investigated. Specifically, your firm received a report that three recipients from one donation that your firm assigned Tissue ID # (b) (4), (b) (6), (b) (7)(C) had post-operative infections. For example, your investigation was limited to confirmation that blood cultures were negative as opposed to evaluating the donor for clinical signs of a systemic infection or diagnoses of sepsis. This is not an all inclusive list.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Shelley H Beausoleil, Investigator
Conor J Mccarron, Investigator
Deepa E Vadakkan, Investigator
Eric Zhu, Investigator

X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 01-15-2026 11:33:50

DATE ISSUED
1/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	1/6/2026-1/15/2026* FEI NUMBER 3000215347

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jennifer K. Prinz, President and Chief Executive Officer	
FIRM NAME Donor Alliance, Inc.	STREET ADDRESS 200 Spruce St Ste 200
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80230-7127	TYPE ESTABLISHMENT INSPECTED Human Tissue Establishment

Your firm's written procedures for screening donors are not designed to ensure donors are screened appropriately.

The deficiencies listed in this observation are examples and do not constitute a comprehensive assessment.

1. When screening a donor of HCT/Ps that will eventually be sent to one of your processors, your firm does not defer a donor (stop recovering that donor) if any of these conditions is specifically diagnosed in the medical record immediately preceding death: sepsis (including, but not limited to, bacteremia, septicemia, sepsis syndrome, systemic infection, systemic inflammatory response syndrome (SIRS) or septic shock). Sepsis is a relevant communicable disease agent or disease (RCDAD).
2. Your firm's procedures do not include the steps to take when your staff reviews the relevant medical records for unexplained clinical evidence and systemic responses to infection, in order to adequately screen a donor for sepsis risk factors.
3. Your firm's procedures are not designed to ensure the hospital records for the donors' hospital stay immediately preceding death are reviewed by a trained and qualified person for clinical evidence of a RCDAD. Current procedures only require the evaluation of clinical signs of a RCDAD observed in the records within (b) (4) of death or the most recent value from the time closest to the donor's death.
4. You have not ensured that, when screening for sepsis, heart rate and respiratory rate are considered.
5. You have not ensured that your procedures are designed to ensure all donors are screened for the more severe signs of sepsis, which include hypoxemia, elevated lactate, oliguria, altered mentation, or hypotension.
6. You have not designed your procedures to ensure donors are adequately screened for risk factors and clinical evidence of West Nile Virus (WNV) and determined unsuitable for recovery, if warranted. For example, your firm doesn't always screen donors for the following clinical

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelley H Beausoleil, Investigator Conor J Mccarron, Investigator Deepa E Vadakkan, Investigator Eric Zhu, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 01-15-2026 11:33:50	1/15/2026

evidence of WNV: a. Mild symptoms including but not limited to fever, headache, body aches, or eye pain; skin rash on the trunk of the body; or swollen lymph glands. b. Severe illness including meningoencephalitis, acute flaccid paralysis, headache, high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions, and muscle weakness or paralysis.

7. Your procedures lack steps to review relevant medical records when hepatomegaly, icterus, and abnormal laboratory values for alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin or prothrombin time are found to determine whether or not such clinical evidence is a risk factor for a RCDAD such as Hepatitis B.
8. Your firm does not have procedures that require you to obtain all required documentation to screen donors for communicable disease risk factors. For example, your procedures allow acceptance of a donor with a history of an animal bite if the animal has documented current rabies vaccination, but your firm has not established procedural steps to obtain documentation supporting vaccination status of the animal.
9. Your firm has not established a procedure that includes all steps necessary to adequately and appropriately evaluate a cadaver for disseminated lymphadenopathy. For example, your procedure does not include which lymph node regions will be evaluated

OBSERVATION 4

Current donor eligibility procedures adopted from another organization were not verified to be consistent with the donor eligibility requirements specified in the regulations and appropriate for your operations.

Specifically, you utilize procedures provided by the tissue processors you are currently in an agreement with to recover tissue for, yet you do not verify that the procedures meet regulatory requirements. The utilized procedures include the steps to screen donors for risk factors and conditions related to relevant communicable disease agents and diseases (RCDADs). You are currently in arrangement with 10 processors in which you have adopted their procedures to screen donors for suitability to proceed with

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	1/6/2026-1/15/2026* FEI NUMBER 3000215347

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jennifer K. Prinz, President and Chief Executive Officer	
FIRM NAME Donor Alliance, Inc.	STREET ADDRESS 200 Spruce St Ste 200
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80230-7127	TYPE ESTABLISHMENT INSPECTED Human Tissue Establishment

recovery.

OBSERVATION 5

Testing for communicable disease agents was not performed in accordance with the manufacturer's instructions.

Specifically, your firm does not store cadaveric blood and serum samples in a temperature monitored environment. The samples are stored in a refrigerator located in the (b) (4) room that is not temperature monitored. Two package inserts reviewed set a temperature range for storage. This is not an all-inclusive list of the temperature storage requirements for specimens used to test donors for relevant communicable disease agents and diseases (RCDAD).

- (b) (4) states (b) (4)
- (b) (4) states (b) (4)

These samples are used to determine the safety and suitability of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for transplant.

OBSERVATION 6

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 store your supplies and reagents at the appropriate storage temperature set forth by the manufacturer.

Supplies and Reagents	Storage Temperature	Rooms Stored In

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	1/6/2026-1/15/2026* FEI NUMBER 3000215347

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jennifer K. Prinz, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Donor Alliance, Inc.	200 Spruce St Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80230-7127	Human Tissue Establishment

Requirement

(b) (4)

The (b) (4) room was not temperature monitored, despite it storing supplies. (b) (4) room has continuous temperature monitoring, but the alarm set points were set at (b) (4) which would not have detected an out-of-range storage temperature. During the months of June, July and August 2025, multiple excursions occurred above (b) (4) in the supply room. Both (b) (4) rooms ((b) (4) and (b) (4)) used for HCT/P recovery are routinely kept below (b) (4) during the year of 2025, with an approximate average temp of (b) (4)

OBSERVATION 7

The quality program has not ensured the proper training and education of personnel involved in core GTP activities.

Specifically, your firm does not ensure Medical Directors and infectious disease consultants involved in donor screening for relevant communicable disease agents and diseases (RCDAD), including sepsis, are trained in core GTP requirements relating to donor screening.

The following are examples of screening activities delegated to Medical Directors or infectious disease consultants who are not trained in your firm's procedures, donor screening requirements, and record keeping practices:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	1/6/2026-1/15/2026* FEI NUMBER 3000215347

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jennifer K. Prinz, President and Chief Executive Officer	
FIRM NAME Donor Alliance, Inc.	STREET ADDRESS 200 Spruce St Ste 200
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80230-7127	TYPE ESTABLISHMENT INSPECTED Human Tissue Establishment

- **Active infection determinations**: Medical Directors have discretion to accept or defer donors exhibiting "active infections," yet your firm has not provided training on these determinations.
- **Sepsis risk assessments**: Medical Directors have discretion regarding donor suitability when sepsis algorithms indicate sepsis risk, yet your firm does not ensure these medical directors receive proper training.
- **Unexplained jaundice evaluations**: Unexplained jaundice is delegated to the discretion of a medical doctor, yet which medical doctor should be contacted has not been established in writing.

***DATES OF INSPECTION**

1/06/2026(Tue), 1/07/2026(Wed), 1/08/2026(Thu), 1/09/2026(Fri), 1/12/2026(Mon), 1/13/2026(Tue), 1/14/2026(Wed), 1/15/2026(Thu)

X Conor J Mccarron
Investigator
Signed By: 2004153102
Date Signed: 01-15-2026 11:34:54

X Eric Zhu
Investigator
Signed By: 2003017579
Date Signed: 01-15-2026 11:35:44

X Deepa E Vadakkan
Investigator
Signed By: DEEPA E. VADAKKAN -S
Date Signed: 01-15-2026 11:37:29

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shelley H Beausoleil, Investigator Conor J Mccarron, Investigator Deepa E Vadakkan, Investigator Eric Zhu, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil -S Date Signed: 01-15-2026 11:33:50	1/15/2026

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."