

CFDP- canine freeze-dried plasma injection, powder, lyophilized, for solution Mantel Technologies

cFDP - Canine Freeze Dried Plasma

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Warnings and Precautions:

For intravenous use in dogs only. Not for use in humans. Keep out of reach of children.

Cutaneous hypersensitivity reactions and vomiting were observed in three studies using this product (see Adverse Reactions).

Do not mix or administer with solutions containing divalent cations (e.g., calcium, magnesium, iron) or synthetic colloids (e.g., hydroxyethyl starch). Do not add medications to the plasma bag. Blood products must be administered using a filter; always use the included blood administration set with integrated 170-260 µm filter when administering cFDP. Do not use this product if the plasma bag is leaking or has been damaged in any way.

cFDP is derived from blood collected from donor animals and may thus contain and transmit infectious agents (see Infectious Disease Risk Mitigation).

Increasing oncotic pressure during administration of cFDP may lead to bleeding at sites not evident at lower blood pressures. The patient should be monitored for transfusion reactions. Signs may include: acute or delayed hemolysis, fever, mild to severe anaphylaxis, transfusion-related acute lung injury, transfusion-associated circulatory overload, endotoxemia or sepsis (e.g., bacterial contamination). In all cases of suspected reactions, stop the transfusion, assess the patient, and follow the recommendations of the attending clinician for supportive care and possible resumption of transfusion.

Safety of cFDP has not been evaluated in dogs less than two years of age or dogs that were breeding, pregnant, or lactating.

cFDP - Canine Freeze-Dried Plasma

Product Description:

The cFDP - Canine Freeze-Dried Plasma Kit (cFDP Kit) contains a sterile, non-pyrogenic, single use, 250 mL allogeneic unit of freeze-dried canine plasma within a protective foil overwrap, a 250 mL Sterile Water for Injection (WFI) diluent bag, and a blood administration set. The cFDP contained within this kit is made from pooled canine plasma from either dog erythrocyte antigen (DEA) I Negative or DEA I Positive dogs. Each kit contains label information stating the blood erythrocyte antigen one status of the pooled plasma, provided as either DEA I Negative or DEA I Positive. A freeze-drying process is used to produce cFDP from canine fresh frozen plasma with minimal reduction in labile coagulation factors that remain within normal canine reference ranges during recommended storage conditions. cFDP requires reconstitution with WFI before

administration to the patient. After reconstitution with provided WFI, the cFDP unit is equivalent to 250 mL of canine fresh frozen plasma. There are no additives or preservatives in this product.

Indications for use:

cFDP is for the treatment of hypovolemia and control of hemorrhage in dogs.

Dosage and Administration:

Requires reconstitution before use. Once reconstituted, this bag is equivalent to 250 mL canine plasma. Administer reconstituted cFDP via intravenous infusion of 10-20 mL/kg body weight at a rate not to exceed 4-6 mL/min. Use the supplied administration line with integrated 170-260 µm filter. For single use only.

After reconstitution, cFDP should be infused immediately but may be stored at room temperature 20-25°C (68-77°F) for up to 180 minutes or stored under refrigeration 1-6°C (34-43°F) for up to 3 days provided cFDP and the kit components are only used one time in a single patient.

Contraindications:

Do not use in patients with history of hypersensitivity to plasma or plasma-derived products.

Infectious Disease Risk Mitigation:

Donor animals were screened and tested for infectious diseases in accordance with FDA CVM Guidance #254, "Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products". Mantel determined eligibility for each individual donor dog based on historical eligibility criteria, health exams, owner questionnaires, complete blood count, biochemical profile, blood typing, and infectious disease testing. These measures are expected to reduce but not eliminate the risk of transmitting infectious disease agents. See the Certificate of Analysis for more information about screening procedures and disease tests performed to determine donor eligibility.

Storage Conditions:

Prior to reconstitution, store in a cool, dry area 1-25°C (34-77°F) out of direct sunlight. Excursions permitted up to 38°C (100.4°F) for 72 hours; however, such exposure should be minimized. Following reconstitution may be stored at room temperature 20-25°C (68-77°F) for up to 180 minutes or may be stored under refrigeration 1-6°C (34-43°F) for up to 3 days provided cFDP and the kit components are only used one time in a single patient.

How Supplied:

cFDP is provided in a single unit kit containing the freeze-dried canine plasma, Sterile Water for Injection USP necessary for reconstitution, and a sterile blood administration set for dispensing. Needle for administration is NOT included. Each component is individually wrapped in sterile barrier packaging. The kit is bundled into a heat-sealed polyethylene bag and transported in a protective cardboard box.

cFDP - Canine Freeze-Dried Plasma

cFDP - Canine Freeze-Dried Plasma Main Product Label



cFDP - CANINE FREEZE-DRIED PLASMA KIT BAG



20 grams of allogeneic canine freeze-dried plasma
For intravenous use in dogs only
For single patient use only

DEA 1 Negative



P1001-1 Rev.1

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Product Description:

This product contains allogeneic canine freeze-dried plasma (cFDP) created from pooled canine plasma that is equivalent to 250 mL canine fresh frozen plasma after reconstitution with provided sterile water for injection.

Indications for use:

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Dosage and Administration:

Requires reconstitution before use. Once reconstituted, this bag is equivalent to 250 mL canine plasma. Administer reconstituted cFDP via intravenous infusion of 10-20 mL/kg body weight at a rate not to exceed 4-6 mL/min. Use the supplied administration set with integrated 170-260 µm filter. For single use only.

See package insert for complete product information, including reconstitution instructions.

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Warnings and Precautions:

Do not mix or administer with solutions containing divalent cations or synthetic colloids. Do not add medications to the plasma bag. Always use the included blood administration set with integrated 170-260 µm filter when administering cFDP. Increasing oncotic pressure during administration of cFDP may lead to bleeding at sites not evident at lower blood pressures. Monitor the patient for transfusion reactions. In cases of reactions, stop the transfusion, assess the patient, and follow recommendations of the attending clinician. cFDP may transmit infectious agents. For intravenous use in dogs only. Not for use in humans. Keep out of reach of children.

Infectious Disease Risk Mitigation:

Donor animals are screened and tested for infectious disease in accordance with FDA CVM Guidance #254, "Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products". Donor screening includes a health exam, owner questionnaire, complete blood count, biochemical profile, blood typing, and infectious disease testing.

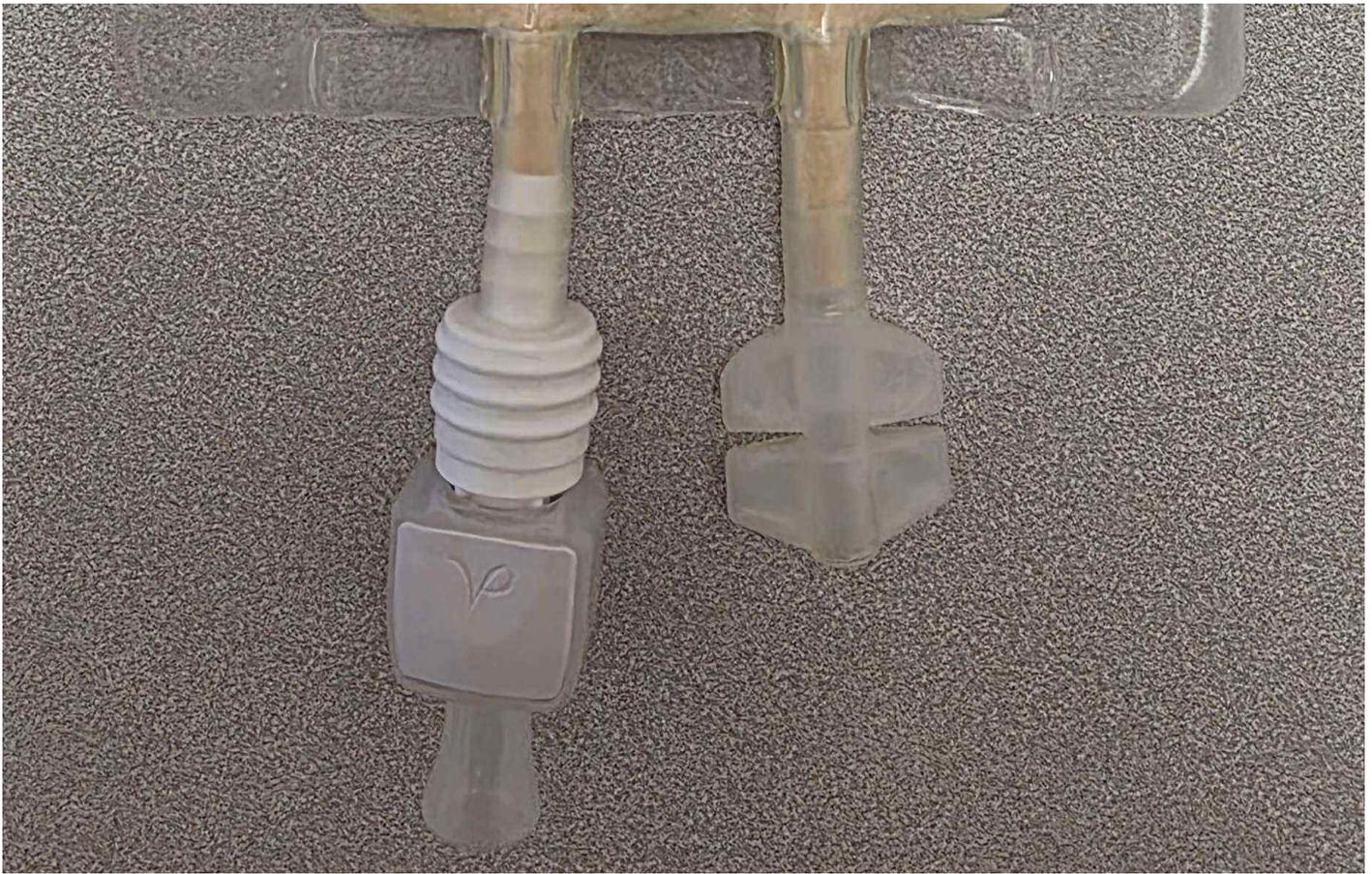
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REF P1001
LOT YYjjjxxxxx-xx
EXP 2026-12-09

FDA risk-reviewed. VMF# 006-295.

Mantel Technologies | 2601 Midpoint Dr. Suite 108 | Fort Collins, CO 80525 USA



CFDP

canine freeze-dried plasma injection, powder, lyophilized, for solution

Product Information

Product Type		Item Code (Source)	NDC:86245-250
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CANINE ALLOGENEIC FREEZE-DRIED PLASMA (UNII: S9490GY42Y) (CANINE ALLOGENEIC FREEZE-DRIED PLASMA - UNII:S9490GY42Y)	CANINE ALLOGENEIC FREEZE-DRIED PLASMA	250 g in 250 g

Product Characteristics

Color	yellow	Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:86245-250-02	1 in 1 BOX		
1	NDC:86245-250-01	250 g in 1 PACKAGE; Number of Units = 250		

cFDP - CANINE FREEZE-DRIED PLASMA KIT BAG



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For intravenous use in dogs only
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P1001-1 Rev.1

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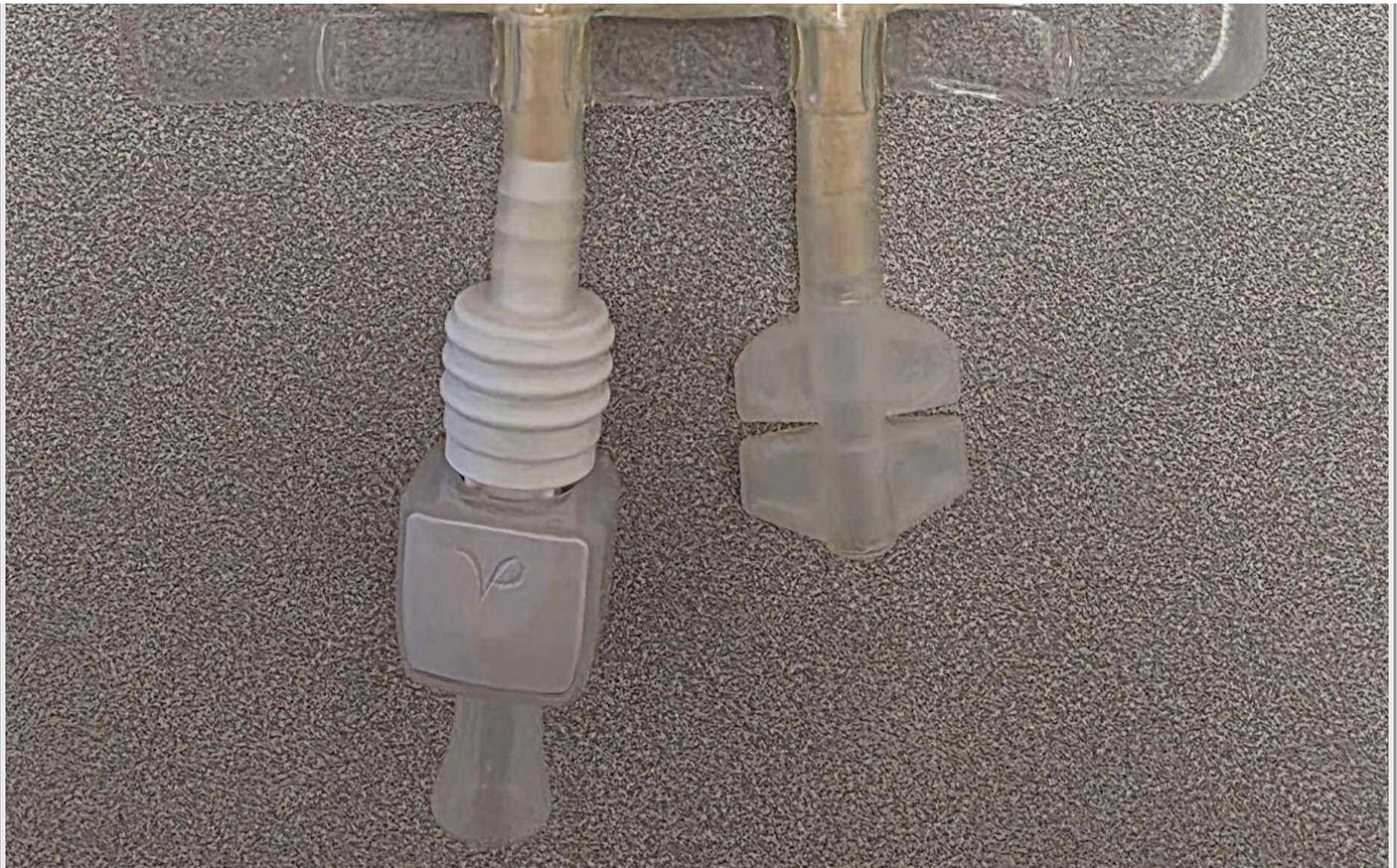
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FDA risk-reviewed. VMF# 006-295.

Mantel Technologies | 2601 Midpoint Dr. Suite 108 | Fort Collins, CO 80525 USA



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/21/2026	

Labeler - Mantel Technologies (078823001)

Registrant - Mantel Technologies (078823001)

Establishment

Name	Address	ID/FEI	Business Operations
Mantel Technologies		078823001	label, analysis, manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Microbial Research		800112836	analysis

Establishment

Name	Address	ID/FEI	Business Operations
Isomedix Operations		144785870	sterilize

Establishment

Name	Address	ID/FEI	Business Operations
Steris Laboratories		613214824	sterilize

Revised: 2/2026

Mantel Technologies