California Animal Blood Banking Guidance Resource

Animal Health and Food Safety Services
Animal Blood Banks Program

Last updated: April 3, 2025

Submit comments on this guidance at any time. Submit electronic comments to CDFAbloodbanks@cdfa.ca.gov or visit https://www.cdfa.ca.gov/AHFSS/CABB/

Submit written comments to:

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Animal Health and Food Safety Services
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I. INTRODUCTION AND SCOPE

The following guidance resource is designed to provide veterinarians clear, accurate, and concise information regarding best management practices for operating blood banks for animals. This document is intended to define current standards of care and practice for veterinary blood banks to ensure that animal blood and blood component products will not only be efficacious, but also not be contaminated, dangerous, or harmful. This guidance document represents the current thinking of the California Department of Food and Agriculture (CDFA) on this topic. Alternative approaches may be permitted if they satisfy the requirements of applicable laws and regulations. To discuss alternative approaches, contact CDFA as listed on the title page.

Animal blood banks must make certain that they follow state and federal laws. A compilation of California statutes dictating how canine blood banking can be performed in the State can be found on the California Legislative Information Website. CDFA also encourages persons developing blood products for animals to email the Food and Drug Administration Center for Veterinary Medicine (FDA CVM) at AskCVM@fda.hhs.gov to learn more about the pathways to legal manufacture and distribution of animal drugs, which includes blood and blood component products for transfusion.

California Food and Agricultural Code (FAC) Division 5, Chapter 1.5 (Commercial Blood Banks for Animals and Biologics) and California Business and Professions Code (BPC) Division 2, Chapter 11, Article 7 (Community Blood Banks for Animals) are the State's legal authority for enforcing state laws and regulations pertinent to animal blood banks. California Code of Regulations (CCR) Title 3, Division 2, Chapter 8 Animal Blood Banks are the regulations adopted by the Department to implement, interpret, and make specific laws related to animal blood banking.

II. DEFINITIONS

Adverse event means an event in which an animal is injured, sickened, unduly stressed or anxious, rendered unconscious, or killed.

Animal includes, but is not limited to, any domesticated fowl or nonhuman mammal or any wild fowl, bird, or mammal that is reduced to captivity.

Biologic means all viruses, serums, antibody products, toxins (excluding substances that are selectively toxic to microorganisms, such as antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and that act primarily through direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.

Best clinical practice means making clinical decisions that are based on up-to-date scientific knowledge. This includes, but is not limited to, guidelines and publications by the American Veterinary Medical Association (AVMA), AVMA-recognized specialty organizations, the Association of Veterinary Hematology and Transfusion Medicine, AVMA-accredited veterinary

colleges, the Association for the Advancement of Blood and Biotherapies, and government organizations.

Blood and blood component products means whole blood collected directly from a donor animal for transfusion or the blood components for transfusion, including red blood cells, platelet-rich plasma, platelet concentrates, fresh plasma, fresh-frozen plasma, frozen plasma, liquid plasma, cryoprecipitate, albumin, and cryosupernatant. This definition excludes platelet-rich plasma for regenerative medicine purposes (osteoarthritis, tendon/ligament injuries, etc.). Antibody products like hyperimmune serums are considered "biologics" and are excluded from this definition of blood and blood component products.

Captive Closed colony means that an animal is kept, housed, confined, or maintained in any way for the purpose of collecting its blood.

Closed colony blood bank means a commercial blood bank for animals that produces animal blood or blood component products solely from animals held in a captive closed colony.

Commercial blood bank for animals means an establishment that produces animal blood or blood component products from closed colony or community sourced animals to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals.

Community blood bank means a commercial blood bank for animals that produces animal blood or blood component products solely from community sourced animals whose owners voluntarily consent to the donation without payment.

Community sourced animal means that an animal is all the following:

- Kept, housed, and maintained at the residence of its owner who is a person and not a partnership, association, corporation, or limited liability company
- Brought by its owner to a community blood bank to have its blood collected
- Licensed in accordance with any pet licensing required by the pet owner's state, county, or city of residence

Payment means the transfer to any person of money or other valuable consideration that can be converted to money by the recipient. For purposes of this document, payment does not include fees for veterinary tests, medications, vaccinations, screenings, or other services that benefit the health of the animal from which the blood or blood component products were taken.

Production means collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for the purpose of transfusion.

Quarterly reporting period means a calendar year quarter. For reporting purposes these shall be January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.

Standards of care means the level of care, skill, and treatment that, in the light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably

prudent licensed veterinarians. This includes, but is not limited to, guidelines published by the American Veterinary Medical Association, the American College of Veterinary Internal Medicine, the California Veterinary Medical Association, AVMA-accredited veterinary colleges, and government organizations.

III. BACKGROUND INFORMATION

As a result of increased specialization in veterinary medicine, the demand for animal blood products has risen dramatically. A safe and adequate supply of blood and blood component products for transfusion is vital to animal health. Commercial blood banks for animals produce and sell blood and blood component products, increasing the supply available for transfusions.

Historically, California required commercial blood banks for animals to be closed colony establishments. On January 1, 2022, Assembly Bill 1282 (2021), the California Pet Blood Bank Modernization Act, went into effect. This law aims to address the shortage of animal blood available for veterinary transfusion medicine in California and transition the State from closed colony blood banks to community blood banks.

Since January 1, 2022, importation and sale of canine blood and blood component products from out-of-state sources have only been permitted from community blood banks (FAC § 9252 (b)). CDFA will discontinue its licensing program for commercial blood banks for animals that produce canine blood and blood component products sourced from captive closed-colony dogs within 18 months of making a finding that community blood banks sold an annual amount of canine blood in California that equals or exceeds the annual amount closed-colony blood banks sold in four consecutive quarters. This will be announced on the CDFA website at https://www.cdfa.ca.gov/AHFSS/CABB/ (FAC § 9212.5(a)).

On July 1, 2025, Animal Blood Bank regulations went into effect. These regulations created clear license, registration, reporting, and fee structures for commercial blood and blood component products.

California licensed veterinarians who collect blood or blood component products solely for use in their own practices must follow current and best practices on animal blood banking (BPC § 4920.2), which includes this guidance document, but are exempt from registering products with CDFA (FAC § 9272(c)).

IV. GENERAL INSTRUCTIONS

Commercial blood banks should operate in accordance with FDA CVM Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products. To the extent possible, establishments should follow the latest human blood banking standards, as published by the Association for the Advancement of Blood and Biotherapies (AABB), formerly the American Association of Blood Banks.

Commercial blood banks must establish, maintain, and follow standard operating procedures (SOPs) for all steps in donor selection, blood collection, testing, storage, and distribution of blood and blood component products. SOPs must be available to personnel in the areas where

they perform such operations. However, SOPs do not have to be physically maintained in the area of operation if such availability is impractical.

The personnel responsible for the collection, testing, storage, and distribution of blood and blood components should be adequate in number, educational background, training, and experience, to ensure competent performance of assigned functions.

Facilities must be maintained in a clean and orderly manner and should be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operation. The facility must provide adequate space for accurate examinations of animals to determine eligibility as donors, blood collection, blood collection equipment, storage of blood components, processing, and labeling operations.

Equipment used in the collection, processing, storage, and distribution of blood and blood component products must be maintained in a clean and orderly manner and located to facilitate cleaning and maintenance. The equipment must be observed, standardized, and calibrated on a regularly scheduled basis, as stated in the facility SOP manual and the manufacturer's instructions for the equipment. All supplies and equipment used should be stored and used in a manner consistent with the instructions provided by the manufacturer.

Commercial blood banks must maintain records regarding each significant step in collecting, processing, testing, storing, and distributing blood and blood component products so that all steps can be clearly traced. All records must be legible and indelible and must identify the person performing the work and dates of various entries. Test results must include interpretation of the result. Records must be as detailed as necessary to provide a complete history of the work performed. Each donor must have a separate and complete record. Establishments may maintain records as hard copies or electronic documents, or a combination of both. Equipment that is necessary to make the records available and legible, such as a computer, should be readily accessible. To ensure the identity, purity, potency, and safety of blood and blood component products; records must be retained 3 (three) years after the date of the product's creation, distribution, disposition, or expiration, whichever is latest.

V. ANIMAL DONOR QUALIFICATION, SELECTION, AND SCREENING

Donor eligibility is critical to ensure the safety and quality of blood and blood component products. A donor should be considered eligible only if screening of the donor shows that the donor is free from risk factors for, and clinical evidence of, relevant diseases or infectious agents. Animal blood banks must have SOPs for determining donor eligibility and final donor eligibility must be determined by a licensed veterinarian. All information contributing to donor eligibility determination must be documented. Exclusion of an animal from a blood donor program does not imply that the animal is sick or in need of treatment for a disease.

A community blood bank may not provide payment to a person who provides the animal for the purpose of donating that animal's blood or blood component products (BPC § 4920.3(a)).

A. Canine Considerations

Enrollment qualification and screening must include, at a minimum, all of the following information for each donor:

- Detailed medical history including:
  - Treatment with cell, tissue, or blood products
    - Having received previous blood or blood component product transfusions disqualifies a donor
    - Having received previous treatment with cell or tissue products (such as stem cells) disqualifies a donor
      - History of treatment with autologous stem cells may be acceptable at the discretion of the blood bank oversight veterinarian
  - Neoplasia
    - History of malignant neoplasia disqualifies a donor
      - Donors with a history of low risk in-situ cancers that have been completely removed and healed may donate at the discretion of the oversight veterinarian
  - Pregnancy
    - Current pregnancy disqualifies a donor
    - Previous pregnancy does not disqualify a donor
  - Heartworm prophylaxis
  - Flea and tick preventive
  - Vaccination history – must be current on regionally appropriate vaccines
    - For dogs in California refer to the University of California, Davis Vaccination Guidelines for Dogs and Cats
  - Current medications
    - Other than flea/tick/heartworm prophylaxis, most other drugs are unacceptable for use during donation periods
    - Supplements, antihistamines, and other routine medications that do not interfere with blood production may be acceptable at the discretion of the blood bank oversight veterinarian and should be defined in SOPs
  - Travel
    - Documented for a period long enough to ensure absence of exposure to relevant disease agents resulting in chronic illness or latent infections
  - In cases where sufficient medical history is not available, donor screening and testing evaluations must be designed to ensure absence of chronic and/or latent relevant disease agents
- Physical examination by licensed veterinarian – annually
- Assessment of temperament to ensure animal will tolerate blood donation
- Confirm identification
- Laboratory evaluation
  - Complete blood count – annually
  - Serum biochemistry profile – annually

    - Bloodborne pathogen screening – annually
        - Minimum testing requirements:
            - *Dirofilaria immitis* – antigen negative
            - *Anaplasma phagocytophilum* – PCR negative
            - *Anaplasma platys* – PCR negative
            - *Babesia (canis) vogeli* – PCR negative
            - *Babesia gibsoni* – PCR negative
            - *Babesia conradae* – PCR negative
            - *Bartonella henselae* – PCR negative
            - *Bartonella vinsonii var. Berkhoffi* – PCR negative
            - *Brucella canis* – PCR negative
            - *Ehrlichia canis* – PCR negative
            - *Mycoplasma haemocanis* – PCR negative
            - *Candidatus Mycoplasma haematoparvum* – PCR negative
            - *Leishmania spp.* – PCR negative
            - Additional testing is at the discretion of the veterinarian overseeing production and should be based on location and travel history of the donor
    - Blood typing
    - Consider screening for von Willebrand factor
        - Some blood banks require vWf:Ag to be > 50%
- Age: Should be 1-8 years old
- Weight: Should be at least 22.7 kg (50 lbs.)
    - Should have a healthy body condition score (BCS)
- Animal source: Must be a community sourced animal
- Written consent of owner

Prior to each blood donation, screening must include, at a minimum, all of the following information for the donor:

- Medical history since last visit/donation:
    - Medical problems or health concerns
    - Heartworm preventive
    - Flea/tick preventive
    - Change in medications
    - Travel
    - Fights/bites
- Confirm identification
- Confirm time since last donation
    - If previous collection volume was less than 10 ml/kg, donations should be at least 2 weeks apart
    - If previous collection volume was greater than 10 ml/kg, donations should be at least 4 weeks apart
- Brief physical exam to include, at a minimum:
    - Temperature, pulse, respirations

    - Mucous membrane evaluation
    - Lymph node palpation
    - No evidence of communicable disease
    - No ectoparasites
    - No evidence of anemia or diarrhea
- Packed Cell Volume (PCV) and total protein or hemoglobin concentration
    - Must be at least 40% PCV and/or 13 g/dL hemoglobin concentration

B. Feline Considerations

Enrollment qualification and screening must include, at a minimum, all of the following information for each donor:

- Detailed medical history including:
    - Treatment with cell, tissue, or blood products
        - Having received previous blood or blood component product transfusions disqualifies a donor
        - Having received previous treatment with cell or tissue products (such as stem cells) disqualifies a donor
            - History of treatment with autologous stem cells may be acceptable at the discretion of the blood bank oversight veterinarian and should be defined in SOPs
    - Neoplasia
        - History of malignant neoplasia disqualifies a donor
            - Donors with a history of low risk in-situ cancers that have been completely removed and healed may donate at the discretion of the oversight veterinarian
    - Pregnancy
        - Current pregnancy disqualifies a donor
        - Previous pregnancy does not disqualify a donor
    - Heartworm prophylaxis
    - Flea and tick preventive
    - Current medications
        - Other than flea/tick/heartworm prophylaxis, most other drugs are unacceptable for use during donation periods
        - Supplements, antihistamines, and other routine medications that do not interfere with blood production may be acceptable at the discretion of the blood bank oversight veterinarian and should be defined in SOPs
    - Housing
        - Donors should be housed in a method that prevents close contact with felines of unknown origin
            - Ideally, donors are housed indoor only and are restricted from close contact with feline housemates that go outside
            - Donors may have controlled outdoor access that prevents close contact with felines of unknown origin, such as balconies or enclosed patios

    - Vaccination history – must be current on regionally appropriate vaccines
        - For cats in California refer to the UC Davis Vaccination Guidelines for Dogs and Cats
    - Travel
        - Documented for a period long enough to ensure absence of exposure to relevant disease agents resulting in chronic illness or latent infections
    - In cases where sufficient medical history is not available, donor screening and testing evaluations should be designed to ensure absence of chronic and/or latent relevant disease agents
- Laboratory evaluation
    - Complete blood count – annually
    - Serum biochemistry profile – annually
    - Bloodborne pathogen screening – annually
        - Minimum testing requirements
            - *Dirofilaria imitis* – antibody negative
            - *Anaplasma phagocytophilum* – PCR negative
            - *Bartonella henselae* – PCR negative
            - *Mycoplasma haemofelis* – PCR negative
            - *Candidatus Mycoplasma haemominutum* – PCR negative
            - *Candidatus Mycoplasma turicensis* – PCR negative
            - *Feline leukemia virus* – PCR negative
            - *Feline immunodeficiency virus* – PCR negative
            - Additional testing is at the discretion of the veterinarian overseeing production and should be based on location and travel history of the donor
    - Blood typing
- Physical examination by a licensed veterinarian
    - Exclude cats with cardiac abnormalities including murmurs or arrhythmias from the donor program unless they have been determined healthy enough to donate blood by a veterinary cardiologist in the last year
- Assessment of donor temperament
    - Donor should not show overt signs of fear or distress
    - If a donor is highly resistant to physical restraint, re-evaluate to determine if the animal is an appropriate candidate for the program
- Age: Should be 1-8 years old
- Weight: Should have lean body weight above 3.6 kg (8 lbs.)
    - Should have a healthy BCS
- Confirm identification
- Written consent of owner

Prior to each blood donation, screening must include, at a minimum, all of the following information for the donor:

- Recent history

    - Medical problems or health concerns
    - Heartworm preventative
    - Flea/tick preventive
    - Change in medications
    - Travel
    - Fights/bites
    - If patient will require sedation or anesthesia, obtain fasting time
- Confirm identification
- Confirm time since last donation
    - Donations should be at least 8 weeks apart
- Brief physical to include, at a minimum:
    - Temperature, pulse, respirations
    - Mucous membrane evaluation
    - Lymph node palpation
    - No evidence of communicable disease
    - No ectoparasites
    - No evidence of anemia or diarrhea
    - Cardiac auscultation
        - Exclude cats with cardiac abnormalities including murmurs or arrhythmias from the donor program unless they have been determined healthy enough to donate blood by a veterinary cardiologist in the last year
- PCV and total protein and/or hemoglobin concentration
    - Should have PCV at least 30% and/or 10 g/dL hemoglobin concentration

VI. BLOOD COLLECTION

A registered veterinary technician or a veterinary assistant may collect blood from an animal for the purpose of transferring or selling the blood and blood component products to a licensed veterinarian at a registered premises, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian (BPC § 4836.5(a)).

Animal blood banks must establish and maintain SOPs for appropriate blood collection from qualified donors. Donor blood is usually collected as whole blood and then separated into components. In certain situations, apheresis may be used to collect single or multiple components. When collecting blood for transfusion products, the collection site must be clipped and aseptically prepared. Blood should be collected into commercially available, sterile, airtight systems that allow for subsequent processing without exposure to the environment. Closed systems should be used when available. To confirm sterility and quality of purchased products, blood banks should perform verification or obtain verification information from vendors.

Collection bags are available in a variety of configurations and sizes. Primary collection bags contain anticoagulant-preservative solutions. Commonly used anticoagulant-preservative solutions include acid-citrate-dextrose (ACD), citrate phosphate dextrose (CPD), citrate phosphate double dextrose (CP2D), and citrate-phosphate-dextrose-adenine-1 (CPDA-1).

Attached satellite bags may contain additive solutions that are composed of varying amounts of adenine, dextrose, sorbitol, sodium chloride, saline, glucose, and mannitol to extend the shelf-life of red blood cells. Common formulations include AS-1 (Adsol ®), AS-3 (Nutricel ®), AS-5 (Optisol ®), and SAGM. Blood banks should only use anticoagulant-preservative solutions and additive solutions where safety is well understood for the intended species.

A. Canine Blood Collection

SOPs for, and documentation of, blood collection must include, at a minimum, all of the following:

- Use of sedatives/tranquilizers/anesthetics if required
  - Most donors do not require chemical restraint
  - Provide protocols including medications used (if applicable)
- Volume of blood collected
  - A maximum of 22 ml/kg of whole blood should be collected at each donation
  - Volume estimated by weight
    - Whole blood weighs 1.06 g/ml
    - Place bag on a traditional scale or use a blood collection mixer scale
    - Up to 10% variation is acceptable
- Venipuncture technique
  - Collection site: Jugular vein is the only recommended site for routine blood donation
  - Venipuncture site must be clipped and aseptically prepared
  - Must obtain smooth, clean entry with rapid blood flow
  - Gravity or light suction may be used
- Collection bag information
  - Type of blood collection kit including manufacturer
  - Anticoagulant-preservative solution used
  - Additive solutions if present
  - Process to ensure adequate mixing of anticoagulant
    - May be accomplished manually by rocking/squeezing bag at least every 60 seconds or use of mechanical agitator or rocking device
- Donor monitoring during and post blood collection must include:
  - Mucous membrane color
  - Pulse rate and strength
    - Mild tachycardia is common
    - If pulse cannot be accurately acquired during blood collection, it should be recorded immediately before and immediately after the donation process
  - Respiratory rate
  - Donor attitude
  - Sedation/anesthetic monitoring if applicable: Pulse oximetry, temperature, blood pressure
  - Criteria for ending procedure
    - May include pallor, stress, discomfort, tachypnea, and tachycardia

- Treatment protocols for adverse events during blood donation
    - May include administration of IV fluids to replace lost volume and monitoring for resolution of clinical signs
- Post collection care and monitoring
    - General well-being of the donor should be ensured before the animal leaves the establishment
        - Donor should be able to walk and maintain normal attitude before release
    - Positive reinforcement for the blood donor is recommended to support future donations
    - There should be follow up to ensure donors were healthy at time of donation, that they recovered well from the procedure, and that they did not experience any adverse events
        - May include contacting owner and/or discussing recovery with owner at next visit for donation
    - If donors do not recover well from the procedure, they should be removed from the donor program

B. Feline Blood Collection

The International Society of Feline Medicine Consensus Guidelines on the Collection and Administration of Blood Products in Cats should be adhered to. SOPs for, and documentation of, blood collection must include, at a minimum, all of the following:

- Use of sedatives/tranquilizers/anesthetics if required
    - Most donors do require chemical restraint to collect blood
    - Provide protocols including medications used (if applicable)
- Volume of blood collected
    - A maximum of 15 ml/kg of whole blood should collected at each donation
        - Total volume per feline donation will likely be 30-50 ml
    - Volume estimated by weight
        - Place bag on a traditional scale or use a blood collection mixer scale
        - 10% variation in volume is acceptable
- Venipuncture technique
    - Collection site: Jugular vein is the only recommended site for routine blood donation
    - Venipuncture site must be clipped and aseptically prepared
    - Must obtain smooth, clean entry with rapid blood flow
    - Light suction or gravity may be used
- Collection bag use and protocols
    - Type of blood collection kit, including manufacturer
    - Volume of collection bag
    - Anticoagulant-preservative solution used
    - Additive solutions if present
    - Process to ensure adequate mixing of anticoagulant
- Donor monitoring during and post blood collection should include:

    - Mucus membrane color
    - Pulse rate and strength
        - Mild tachycardia is common
    - Respiratory rate
    - Donor attitude
    - Sedation/anesthetic monitoring if applicable: Pulse oximetry, temperature, blood pressure
    - Criteria for ending procedure
        - May include pallor, stress, discomfort, tachypnea, tachycardia, or other anesthetic complications
- Treatment protocols for adverse events during blood donation
    - May include administration of IV fluids to replace lost volume and monitoring for resolution of clinical signs
- Post collection care and monitoring
    - General well-being of the donor must be ensured before the animal leaves the establishment
    - Some protocols include administration of intravenous or subcutaneous fluids
    - There should be follow up to ensure donors were healthy at time of donation, that they recovered well from the procedure, and that they did not experience any adverse events
        - May include contacting owner and/or discussing recovery with owner at next visit for donation
    - If donors do not recover well from the procedure, they should be removed from the donor program

VII. PROCESSING WHOLE BLOOD AND SEPARATION INTO COMPONENTS

SOPs for processing blood products should follow validated or verified processes, such as those published by the AABB or the Association of Veterinary Hematology and Transfusion Medicine (AVHTM). SOPs must provide descriptions of equipment used, including but not limited to, the following:

- Centrifuges
- Blood bags
- Blood transfer bags
- Scales
- Blood bag tube strippers
- Blood bag tube sealers
- Blood bag tube welders
- Anticoagulant-preservative solutions
- Additive solutions
- Plasma extractors
- Blood filters
- Refrigerators
- Freezers

Use of processing techniques such as pooling of blood from multiple donors, leukoreduction, irradiation, ultraviolet treatment, or photochemical treatment must be stated in SOPs.

A. Whole Blood

SOPs for processing whole blood must include, at a minimum, all of the following:

- Handling from collection to storage or transportation
- Documentation of temperature during process
- Addition of anticoagulants and additive solutions
- Process for tube clamping and sealing, including number of segments
- Time from collection to refrigeration
- Acceptable temperature during storage and/or transport to purchaser
- Application of labels
- Retention of a sample from each unit produced for additional testing and quality control purposes

B. Red Blood Cells

SOPs for processing red blood cells must include, at a minimum, all of the following:

- Handling of whole blood to processing
- Time from collection of whole blood to processing
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
- Centrifuge temperature
- Method for plasma removal
- Process for adding anticoagulants and additive solutions
- Process for tube clamping and sealing, including number of segments
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

C. Platelet-Rich Plasma

SOPs for processing platelet-rich plasma must include, at a minimum, all of the following:

- Time from collection of whole blood to processing
- Handling of whole blood to processing of platelet-rich plasma
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
- Centrifuge temperature
- Method for platelet-rich plasma extraction
- Process for blood tube clamping and sealing, including number of segments

- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Method of checking for bacterial contamination (such as bacterial culture)
- Retention of a sample from each unit produced for additional testing and quality control purposes

D. Platelet Concentrate

SOPs for processing platelet concentrate must include, at a minimum, all of the following:

- Clear indication of method used, such as platelet-rich plasma or buffy-coat method
- Handling of platelet-rich plasma or whole blood to processing platelet concentrate
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
- Centrifuge temperature
- Method for platelet-poor plasma extraction
- Method used to promote disaggregation and resuspension of platelet concentrate
- Method of checking for bacterial contamination (such as bacterial culture)
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

E. Fresh-Frozen Plasma

SOPs for processing fresh-frozen plasma must include, at a minimum, all of the following:

- Time from collection of whole blood to processing
    - Must be separated from whole blood within 8 hours of collection and quick-frozen within 1 hour of separation
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
- Centrifuge temperature
- Method for plasma removal
- Process for blood tube clamping and sealing, including number of segments
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

F. Frozen Plasma

SOPs for processing frozen plasma must include, at a minimum, all of the following:

- Time from collection of whole blood to processing
- Centrifugation revolutions per minute or acceleration (expressed as *g*)

- Centrifugation time
- Centrifuge temperature
- Method for plasma removal
- Process for blood tube clamping and sealing, including number of segments
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

SOPs for converting fresh-frozen plasma to frozen plasma must include, at a minimum, all of the following:

- Criteria for converting fresh-frozen plasma to frozen plasma
    - Should include fresh-frozen plasma units stored longer than 1 year OR
    - Fresh-frozen plasma units stored under refrigeration longer than 24 hours before transfusion
- Process for relabeling fresh-frozen plasma
- Retention of a sample from each unit produced for additional testing and quality control purposes

G. Cryoprecipitate

SOPs for processing cryoprecipitate must include, at a minimum, all of the following:

- Process for thawing fresh-frozen plasma including temperature and time
    - Should be slow thawed at 1-6°C
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
- Centrifuge temperature
- Method for plasma removal
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

H. Cryosupernatant

SOPs for processing cryosupernatant must include, at a minimum, all of the following:

- Process for thawing fresh-frozen plasma including temperature and time
    - Should be slow thawed at 1-6°C
- Centrifugation revolutions per minute or acceleration (expressed as *g*)
- Centrifugation time
    - Time should include acceleration time but not deceleration time
- Centrifuge temperature
- Method for plasma removal

- Process for blood tube clamping and sealing, including number of segments
- Application of labels
- Acceptable temperature during storage and/or transport to purchaser
- Retention of a sample from each unit produced for additional testing and quality control purposes

VIII. LABELING

All labeling must be truthful and not misleading. Labels for blood and blood component products must contain, at a minimum, all of the following:

- Name and address of manufacturer
- Establishment license number
- Product name
- Blood type
- Use of leukoreduction (if applicable)
- Donor species
- Collection date
- Expiration date
- Volume
- Anticoagulant and additive solution information
- Appropriate storage conditions
- An identifying lot or control number from which it is possible to determine the complete manufacturing history of the product
    - Each tube segment must have identifying lot or control number
- Donor ID

The product insert should contain all of the following information if it cannot be reasonably placed on the label:

- Use (single v. multi use)
- A statement to indicate the product is limited to veterinary use only
- A statement that the product is for IV use in [insert species] only
- Product description
- Indication
- Directions
- Dosage information
- Donor eligibility
- Contraindications
- Precautions
- Warnings
- Contact information for reporting adverse events and product defects to the manufacturer
- The statement “For additional information about adverse drug experience reporting, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae”

IX. STORAGE

Animal blood and blood component products must be stored in an appropriate manner to prevent mix-ups, contamination, and cross-contamination, and in a manner that does not compromise the quality of the product.

Refrigerators and freezers used in the storage of blood products must be designed to ensure proper temperature is maintained. The temperature of the storage device must be routinely monitored with readings recorded on an established schedule. Storage devices should be outfitted with alarms to indicate unsafe temperatures. Alarms should also sound in the event of other factors that could impact temperature, such as door opening and power failure. Backup power sources, such as uninterruptible power supplies and backup generators, should be considered to ensure that blood and blood component products are not compromised during power failures.

Blood and blood component products decline in quality and effectiveness over time. Expiration dates can vary depending on species, type of anticoagulant used, additive solutions, and storage conditions. Storage SOPs must include storage temperatures, methods for monitoring temperature, and length of time products will be stored for. Acceptable expiration dates for common animal blood and blood component products are listed in the table below.

A. Table of Expiration Dates

The expiration date for products must not exceed the value listed below, unless a different dating period is specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by CDFA.

Product	Storage Temperature	Expiration Date
Whole blood with anticoagulant ACD, CPD, or CP2D	1-6 °C	21 (ACD) and 28 (CPD, CP2D) days from date of collection
Whole blood with anticoagulant CPDA-1	1-6 °C	35 days from date of collection
Red blood cells with anticoagulant ACD, CPD, or CP2D	1-6 °C	21 days (ACD) and 28 (CPD, CP2D) from date of collection
Red blood cells with anticoagulant CPDA-1	1-6 °C	35 days from date of collection
Stored red blood cells with additive solutions (AS-1, AS-3, AS-5, SAMG)	1-6 °C	42 days from date of collection

Frozen red blood cells	≤ -65 °C	10 years from date of collection
Platelet-rich plasma	20-24 °C	7 days from date of collection. Should have continuous gentle agitation
Platelet concentrate	20-24 °C	7 days from date of collection. Should have continuous gentle agitation
Cryopreserved platelets in DMSO	-20°C	180 days from date of collection
Cryopreserved platelets in DMSO	-80°C	2 years from date of collection
Fresh-frozen plasma	≤ -18 °C	1 year from date of collection
Frozen plasma	≤ -18 °C	5 years from date of collection
Cryoprecipitate	≤ -18 °C	1 year from date of collection
Cryosupernatant	≤ -18 °C	5 years from date of collection

X. SHIPMENT OF PRODUCTS

Blood and blood component product packaging and shipping containers must be designed and constructed to protect the product from contamination and to maintain quality. Appropriate shipping conditions must be maintained during transit and distribution. Validated shippers for human blood products or self-validated shippers should be used. SOPs for shipment of blood and blood component products must include:

- Evaluation of each outgoing product for damage, quality, and contamination
- Materials used
- Method for tracking shipments
- Transportation companies used
- Acceptable temperature range during shipment
- Method for ensuring products remain at acceptable temperature range during shipment

If returns are not permitted, this must be made clear to the consignee. If returns are permitted, conditions under which the return could be accepted must be specified.

XI. QUALITY ASSURANCE

Animal blood banks must have a quality assurance program designed to prevent, detect, and correct deficiencies that may lead to circumstances that increase the risk of introduction of contamination or impact product quality. SOPs for receiving, investigating, evaluating, and documenting information related to complaints and adverse events are required. Complaint files must contain sufficient information for review and evaluation and for determining whether the complaint is an isolated event or indicates a trend.

XII. LICENSING AND PRODUCT REGISTRATION

Community blood banks operating in California must register with the California Veterinary Medical Board (BPC § 4920.4). Additionally, no person shall offer for sale any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture (FAC § 9241(a)).

Blood banks must register all animal blood and blood component products with the CDFA (BPC § 4920.5). Registration must be renewed annually. An application for registration of blood or a blood component product shall include all the following (FAC § 9244 (a) (1-6)):

- The name and address of the person who owns the property, establishment, institution, or business that sells the blood
- The name and address of the person who oversees the production of animal blood and blood component products
- The type of animal blood and blood component products produced for sale
- A full description of the building, including its address, facilities, equipment, and apparatus, to be used in production of animal blood and blood component products
- A protocol for the methods of production in detail that is followed in the production of the product
- A sample of the label to be placed on the blood or blood component product
- Any change in the information contained in the product registration application or product registration renewal application must be reported to the Department within thirty (30) calendar days of such change (CCR § 1304.3)

A. Fees

The registration application fee or annual renewal fee for an establishment proposing to offer blood or blood component products for retail sale or use in California are as follows (FAC § 9244 (b)(1-4)):

- The registration application fee and annual renewal fee shall be five hundred and forty-four ($544) for each product, which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year (CCR § 1307.2 (a)(2))
- Registration shall be renewed every year. The annual renewal fee shall be paid on or before July 1 of each year
- The application and renewal fees shall be adjusted annually for inflation

In addition to the registration application fee and annual renewal fee required by FAC § 9244, commercial blood banks for animals with products registered by the Department shall pay a registration fee of five cents ($0.05) per milliliter (ml) blood and blood component products sold in this State, as reported on quarterly reports (CCR §1307.1).

- These fees shall be paid to the Department quarterly, at the time of submission of quarterly reports
- This fee shall be adjusted annually for inflation

XIII. SALE OF PRODUCTS

A commercial blood bank for animals shall not discriminate against veterinarians licensed in California in the sale of animal blood or blood component products (FAC § 9222 (a)). For instance, a commercial blood bank that refuses to sell animal blood or blood component products to a veterinarian in circumstances in which that blood bank has available supply may be deemed to be in violation of this provision.

XIV. INSPECTIONS AND QUARTERLY REPORTING

The Department, or humane officers under contract with the Department, shall inspect commercial blood banks with blood or blood component products registered with the Department at least once a year to ensure compliance with protocols required by FAC § 9244(a). Additional inspections may be required to investigate complaints of noncompliance (CCR § 1306.3).

Records must be maintained onsite and available for inspection by the Department or the Veterinary Medical Board. Records must include information related to the following (BPC § 4920.2 (g) and (h)):

- History of blood draws
- Use of anesthesia on the animal
- Number and date of donations collected
- Estimated milliliters of blood collected per donation based on weight in grams
- Any adverse events
- Any complaints from owners regarding animals who donate blood or blood component products
- Written consent of owner of the animal blood donor

Animal blood banks that sell products in California are required to submit quarterly reports to CDFA that include all the following (BPC § 4920.6 (a-d)):

- The number of donations from community sourced animals
- Separate total amounts of whole blood, red blood cells, and frozen plasma sold in California during that quarter, by species of animal in estimated milliliters based on weight in grams

- The number and species of animal donors experiencing adverse events, the total number of adverse events, and the nature of adverse events experienced by animals that donate blood
- The number and species of animal donors that have donated blood
- The number and species of animal donors whose blood tested positive for known pathogens
- Payment of $0.05 per milliliter (ml) blood and blood component products sold, as reported on quarterly reports submitted to the Department (CCR § 1307.1)

Quarterly reports and fees must be postmarked or electronically submitted no later than 45 calendar days after the end of the quarter (CCR § 1305.2).

XV. REFERENCES

1. Abrams-Ogg, A.C.G. and Blois, S.L. (2022). Principles of Canine and Feline Blood Collection, Processing, and Storage. In Schalm's Veterinary Hematology (eds M.B. Brooks, K.E. Harr, D.M. Seelig, K.J. Wardrop and D.J. Weiss)
2. Gammon, RR. *Standards for Blood Banks and Transfusion Services.* 33rd ed. Association for the Advancement of Blood and Biotherapies; 2022.
3. Cohn, CS. *Technical Manual (AABB).* 20th ed. American Association of Blood Banks; 2020.
4. Yagi K, Holowaychuk MK. *Manual of Veterinary Transfusion Medicine and Blood Banking*. Ames, IA: Wiley Blackwell; 2016.
5. Wardrop KJ, Birkenheuer A, Blais MC, et al. Update on Canine and Feline Blood Donor Screening for Blood-Borne Pathogens. *J Vet Intern Med*. 2016;30(1):15-35. doi:10.1111/jvim.13823
6. Taylor S, Spada E, Callan MB, et al. 2021 ISFM Consensus Guidelines on the Collection and Administration of Blood and Blood Products in Cats. *J Feline Med Surg*. 2021;23(5):410-432. doi:10.1177/1098612X211007071
7. Davidow EB, Blois SL, Goy-Thollot I, et al. Association of Veterinary Hematology and Transfusion Medicine (AVHTM) Transfusion Reaction Small Animal Consensus Statement (TRACS). Part 1: Definitions and clinical signs. *J Vet Emerg Crit Care (San Antonio)*. 2021;31(2):141-166. doi:10.1111/vec.13044
8. Davidow EB, Blois SL, Goy-Thollot I, et al. Association of Veterinary Hematology and Transfusion Medicine (AVHTM) Transfusion Reaction Small Animal Consensus Statement (TRACS) Part 2: Prevention and monitoring. *J Vet Emerg Crit Care (San Antonio)*. 2021;31(2):167-188. doi:10.1111/vec.13045
9. Odunayo A, Nash KJ, Davidow EB, et al. Association of Veterinary Hematology and Transfusion Medicine (AVHTM) transfusion reaction small animal consensus statement (TRACS). Part 3: Diagnosis and treatment. *J Vet Emerg Crit Care (San Antonio)*. 2021;31(2):189-203. doi:10.1111/vec.13043
10. Food and Drug Administration Center for Veterinary Medicine. *CVM GFI #254 Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products*. 2021.FDA-2021-D-0401
11. Food and Drug Administration Center for Veterinary Medicine. *CVM GFI #218 Cell-Based Products for Animal Use*. 2015. FDA-2014-D-0634.