

Technical Bulletin

Australian Sourced Donor Bovine Serum

Control over the collection and processing procedures of blood from donor bovines provides the following benefits:

- Shorter processing time;
- Reduction of the risk of contamination with impurities such as water and animal stomach contents which may be present at abattoir collections;
- Better temperature control throughout collection;
- Cleaner working environment; and
- Control over personnel operating in the collection and processing areas.

At an abattoir when an animal is killed, the body goes into an extreme state of trauma. Toxins that are instantly released into the blood system can have an inhibitory effect on the cell culture quality of serum. Trauma does not occur during donor collection, therefore the serum is of higher quality and potentially supports a greater level of cell growth.

Donor serum is processed from blood of healthy, nutritionally sound animals that are fed up to the time of collection. Animals at abattoirs vary greatly in health and nutritional history. They often fast prior to slaughter, which can cause certain nutrients in the blood to be at reduced levels at the time of collection.

Donor Source

The herd of donor bovines is located on a 600 acre farm in New South Wales, Australia. Collection, processing and storage facilities are on the same land as the cattle. The farm operation does not have multiple collection or processing sites and all donor products are collected on-site.

The closed, virus-free herd of cattle is kept away from all other outside livestock. Donors routinely undergo veterinary inspections. Prior to placement within the herd, potential donors are quarantined and blood samples are taken from each animal.

Donors are screened for:

- Blue Tongue (BT)
- Enzootic Bovine Leukosis (EBL)
- Infectious Bovine Rhinotracheitis (IBR)
- Bovine Viral Diarrhea (BVD)
- Parainfluenza Type 3 (PI3)

Records are maintained to identify each donor that contributed to the pool and the day the individual collection was performed. A Certificate of Origin signed by a veterinarian employed by the government of Australia confirming that the serum is of Australian origin accompanies each batch of raw serum.

Australia is considered to be free of:

- Bovine Spongiform Encephalopathy (BSE)
- Bovine Rabies
- Foot and Mouth Disease (FMD)
- Rinderpest
- Anthrax
- Vesicular Stomatitis

Animal Husbandry

Donors are from mixed breeds, male and female, and range in age up to 8 years old. Calves remain with their mothers, but are not bled prior to weaning. After weaning and virological screening, they are transferred to the appropriate herd, and included in the bleeding programs.

Donors graze, free range. If needed, supplementary feeding consists only of hay, grain or silage. No animal byproducts are fed to livestock.

Donor animals are inspected regularly by an Australian Quarantine Inspection Services (AQIS) approved veterinarian

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and certified to be healthy and free of disease by clinical inspection.

- All illnesses are documented and reviewed by the veterinarian.
- Donor animals are not vaccinated.
- Donors are not bled for 7 days after worming or for 30 days after antibiotic treatment.
- All mortalities are identified and, if appropriate, necropsies are conducted.
- Cows are inspected twice daily during the calving season.

Strictly controlled quarantine pens where animals cannot come into contact with outside animals are available for:

- New animals (either purchased outside or animals born at the donor farm) during virological screening prior to introduction into the donor herds;
- Animals receiving medical treatments;
- Animals suspected of having a contagious disease; and
- Any animal showing clinical signs of infection as determined by veterinary inspection.

Blood Collection & Raw Serum Processing

Donors are bled at regular intervals not to exceed 4 times per 28 days. The volume of blood taken at collection from each donor is based on the weight of the animal, approximately 1 liter/kg.

Each donor must meet certain criteria in order to be bled. These include:

- Packed cell volumes;
- No antibiotic treatment within previous 30 days;
- No serious cuts, abscesses or infections;
- Not about to calve or having just calved;
- Animal appears healthy and alert; and
- Animal is in good to prime condition and not rapidly losing weight.

Collection of whole blood occurs on a regular basis. The blood is collected from the jugular vein of individual animals, mechanically defibrinated and passed through continuous flow centrifuges at 4 C. The pooled raw serum is then dispensed, labeled and frozen at -20 C. The entire procedure from blood collection to storage takes less than 12 hours.

Serum Filtration

Filtration occurs at SAFC Biosciences, Brooklyn, Victoria, Australia, or in Lenexa, Kansas, USA. Raw serum is thawed under controlled conditions and immediately passed through

a series of descending porosity filters and a sterilizing filter, into a stirred, refrigerated, pre-sterilized holding tank, creating a homogeneous true pool. Serum is then dispensed into sterile plastic containers, capped, labeled, tamper evidence sealed and placed in a secure freezer at -10 to -40 C until Quality Control testing has been completed.

USA Importation

When donor bovine serum is imported into the USA for distribution, it is quarantined upon receipt at the SAFC Biosciences' facility in Lenexa, Kansas. This facility is routinely inspected by the United States Department of Agriculture (USDA) and is an approved USDA quarantine location.

Samples from each lot imported are removed by a USDA official and submitted to the Center for Veterinary Biologics Laboratory (CVBL) in Ames, Iowa for safety testing according to current Ruminant Serum (RS) Import Requirements. Serum sourced and processed in Australia is screened for antibodies against Blue Tongue Virus by agar gel immunodiffusion and for Akabane by serum neutralization test. Results provided by the USDA/CVBL are reported on each lot-specific Certificate of Analysis provided by SAFC Biosciences.

For more information about this subject or any other SAFC Biosciences products or services, please contact Technical Services.

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