

Technical Bulletin

Importation of Fetal Bovine Serum from SAFC Biosciences - Australia

All filtered Australian Fetal Bovine Serum (AFBS) is tested by SAFC Biosciences/Kansas Quality Control (QC) and released by SAFC Biosciences/Kansas Quality Assurance (QA) per established specifications.

Bulk AFBS is held in inventory in Australia pending worldwide distribution requirements. Stock inventory requirements in the USA are evaluated and, as needed, orders are raised for specific lots and volumes to be imported.

SAFC Biosciences/Australia compiles the necessary documentation and ships product packed with dry ice via airfreight from Melbourne, Australia. The documentation includes a Declaration & Certificate, signed by a Veterinary Officer of the Australian Government, Department of Primary Industries and Energy. This certificate is prepared only upon satisfactory submission of a statutory declaration from SAFC Biosciences/Australia confirming traceability of all serum contained within the lot as sourced from export registered abattoirs.

Product is quarantined by United States Department of Agriculture (USDA) at the US port of entry, which is typically Los Angeles. Quarantine includes: inspection of documentation (Import Permit Number FBS-374), condition of product, and sealing of all boxes with USDA quarantine tape.

Customs clearance occurs at the USA port of entry, and final transportation of the product to SAFC Biosciences/Kansas is arranged.

USDA Area Office Official breaks seals on shipping boxes when received at SAFC Biosciences/Kansas warehouse. The product is inspected and stored in USDA approved quarantine location within the SAFC Biosciences/Kansas freezer.

USDA Area Office Official removes appropriate number of containers to be sampled as required for safety testing by the USDA Lab in Ames, Iowa. The number of containers

depends upon the entire volume imported; for instance, bulk AFBS lots in excess of 2000 x 500 mL bottles require 57 bottles be removed at USDA discretion for statistically valid sampling.

Bottles isolated by the USDA are thawed and pooled for submission to USDA. This safety testing takes approximately five weeks.

Per USDA, Veterinary Services (VS) Notice 98-05, Ruminant Serum (RS) Import Requirements, safety testing guidelines include:

The fetal bovine serum sample submitted is inoculated into 3 sheep by the subcutaneous route. Serum from the sheep is tested for antibodies against bluetongue virus (BTV) by agar gel immunodiffusion and for Akabane by the serum neutralization test on the day of inoculation and at 28 days post inoculation (DPI). Results are reported in writing via a USDA Laboratory Findings Final Report.

Upon receipt of satisfactory USDA report, SAFC Biosciences issues a Certificate of Analysis for the specific FBS lot indicating USDA safety testing results, and releases product from quarantine status; distribution of product occurs as required.

General

SAFC Biosciences/Kansas is ISO 9001 certified, GMP compliant and FDA inspected as a Class 1 Medical Device Manufacturer. The facility is also routinely inspected by the USDA, including review of documentation, sample handling and quarantine locations.

SAFC Biosciences/Australia is ISO 9002 certified, GMP compliant and Therapeutics Goods Association (TGA) inspected.

All fetal blood is collected from Australian Quarantine Inspection Service (AQIS) inspected abattoirs in Australia.

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Australia is recognized by the USDA as being free of Foot and Mouth Disease (FMD), Rinderpest and Bovine Spongiform Encephalopathy (BSE).

An SAFC Biosciences' Certificate of Analysis accompanies each batch of Australian FBS.

For more information about this subject or other SAFC Biosciences' products and services, please call our Technical Services department or e-mail us at technicalservices@sial.com.

Warranty, Limitation of Remedies

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Additional Terms and Conditions are contained in the product Catalog, a copy of which is available upon request.

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