

HyClone sera, Australian origin



Australian methods of animal husbandry exhibit excellent animal nutrition and healthcare. As with New Zealand, Australia is an island continent, making animal disease control and management easier than in most areas of the world. Cytiva's Australia origin fetal bovine serum (FBS) is only sourced from abattoirs in Australia that are export eligible by the U.S. Department of Agriculture (USDA) and approved by the Australian Department of Agriculture (DA).

HyClone™ Australia origin characterized FBS is manufactured in Tauranga, New Zealand using our single-use manufacturing system according to strict manufacturing and quality control procedures for consistency, high quality, and dependable cell performance.

HyClone Australian FBS is manufactured using single-use systems and true pool technology to offer lot-to-lot consistency. Single-use processing of Australian FBS ensures product integrity, reducing cross-contamination with other serum products.

Tauranga, NZ facility and equipment

- Single-use technology
- 2000 L capacity (1000 L production volume)
- Filtration options
 - Sterile triple 0.1 µm

Capabilities and support services

- Standard, validated treatments including gamma-irradiation
- Expert team of serum technical sales representatives
- Reserve programs available
- Wide range of standard serum testing
- Non-standard testing available upon request

Quality assurance

- Audited by the DA
- Subject to unannounced audits by regulatory agencies
- cGMP (21 CFR 820) compliant
- Validated inventory control system
- Complaint management and resolution
- Global import permits exist with successful track record

Clean room

- LAF (laminar flow hood) is classified as ISO class 5 (class 100)
- Main clean room is classified as ISO class 6 (class 1000)
- Anterooms are ISO class 7 (class 10 000)

Freezing

- Product is labeled and shrink banded
- Product is frozen to $\leq -10^{\circ}\text{C}$
- Bottles are placed into blast freezer where the newly filtered serum is frozen

Storage

- Frozen serum is packed into cartons and transferred to storage freezer where it awaits shipping

Serum supply chain:

Collection	Processing	Filtration	Bottling
Raw material is collected	Product separation via Cytiva's contracted partners Raw serum moves to filtration	Raw serum filtered utilizing true pool technology	Processed serum bottled and stored

 Outsourced
 In-house

Characterized FBS, Australian Origin is sourced from Australian abattoirs approved by the USDA or DA

Traceability

Cytiva sources Australian raw serum materials from multiple qualified Australian sources in compliance with applicable veterinary control authorities to increase supply availability. The serum origin is defined as the country in which the raw material was collected (i.e., serum origin does not refer to the country where the raw serum was sterile filtered). Accompanying documentation for all Australian FBS batches includes certificates of analysis and, if irradiated, certificates of irradiation upon request. A verifiable document trail for your serum to the geographic origin and source of the raw material used in production is available.

[cytiva.com/hyclone](https://www.cytiva.com/hyclone)

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