

HyClone sera, US origin



Cytiva's US, USDA-tested, and Canada origin serum products are manufactured in the North American facility in Logan, Utah, in accordance with strict manufacturing and quality control procedures. These procedures offer customers product consistency, high quality, and dependable cell performance. The serum products are manufactured in large batch sizes using true pool technology to offer lot-to-lot consistency.

In-country processing of US origin fetal bovine sera (FBS), bovine calf sera, engineered sera, and other serum source products is optimized for integrity and to minimize risk of cross-contamination with other serum origins. Non-US origin products are manufactured in a separate facility utilizing single-use technology to minimize risk of cross-contamination with other serum products.

Utah, US facility and equipment:

- Stainless steel equipment
- Single-use technology
- 3000 L lot capacity for US FBS
- 2000 L lot capacity for USDA-tested and Canada origin FBS
- Filtration options include:
 - Sterile 0.04 µm
 - Sterile 0.2 µm
 - Sterile triple 0.1 µm

Capabilities and support services:

- Standard, validated treatment options including gamma-irradiation and heat inactivation
- Specialty FBS treatments and screening options
- Serum reserve program
- Expert team of serum technical sales representatives
- Wide range of standard serum testing
- Non-standard testing available upon request

Quality assurance:

- Routine quality and customer audits
- cGMP (21 CFR 820) compliant
- Validated inventory control system
- Complaint management and resolution
- Quality Assurance/Regulatory Affairs
- Global import permits exist with successful track record
- ISO 9001, ISO 13485 certified

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 (less than or equal to) -10°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

Traceability

Cytiva sources raw serum materials from multiple sources and geographies in compliance with applicable veterinary control authorities to offer a choice of serum origins and to increase supply availability. 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 batches includes certificates of analysis and, if irradiated or heat inactivated, certificates are available upon request, certificates of heat inactivation upon request. A verifiable document trail for your serum to the geographic origin and source of the raw material used in production is available.

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