

Standard Certificate of Analysis:

Each lot/batch of final-filtered Fetal Bovine Serum must be subjected to the minimum panel of required product integrity and species identity tests as outlined above before it is released for distribution to the end-user. These tests must be documented and summarized in a Certificate of Analysis that is made available to the customer with each lot/batch purchased.

The Certificate of Analysis must (1) list the name of each quality control test performed; (2) clearly document the test method used; and (3) display the specification or acceptability range for the test, the unit of measure and the result.

Furthermore, the Certificate of Analysis must supply, at a minimum, the following additional information pertaining to the lot/batch:

- Company Name, Address and Contact Information of Supplier
- Product Name, Catalog Number, Lot/Batch Number
- Manufacture Date
- Expiration Date
- Intended Use
- Raw Material Country(ies) of Origin
- Date and (electronic) Signature (QC Department)

ISIA recommends that every participating organization also list the Country of Final Processing, Filtration Data, and Storage Conditions.

Every organization may also list on their Certificates of Analysis additional QC tests performed as well as additional information, depending on their individual requirements, and may also select their own format.

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