Traceability
An important risk mitigation program
17 steps
3 sets of QC tests
# Modular Audit Focus

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Why the program works!

- Covers all aspects of what happened to the product every step of the way from the abattoir to the customer
- Covers all transactions in the company
  - Not just those for a specific customer
- Focuses on each handoff
  - Not a financial audit but
    - What came in at what price?
    - What went out at what price?
How the Program works!

• Independent Third-Party Audit
  • Performed by an ISIA approved/trained auditor
  • To an ISIA approved audit plan
  • Using a detailed ISIA audit checklist

• Modelled after ISO audits

• Involved origin testing of auditor selected batches

• Initial certification requires at least one year of data
Traceability

- Suppliers are certified for the piece of the process they perform
  - One step or all steps
- Certification not available for purchase
  - You must meet ALL the requirements
    - Ordering and shipment audits for distributors
- Certification is granted for three years
Traceability Certified Companies

- Animal Technologies Inc.
- Atlas Biologicals
- AvantorSciences
- Axenia BioLogix
- BioMin Biotechnologia S.A.
- By Productos S.A. de C.V.
- Central Biomedia Inc
- Corning Inc.
- Cytiva HyClone
- Gibco Thermo Fisher Scientific
- Life Science Production Group
- Moregate Biotech
- Newman Biotech Australia
- Orygina a JBS Company
- River City Biologicals
- River City Biotecnologia Ltda.
- Rocky Mountain Biologicals
- SeraTec LLC
- TCS Biosciences, Ltd

Others in process
Recognition by Government Regulators

• This program is recognized by government regulators world-wide as one that contributes to the integrity of serum distribution and the serum industry in general.

• Many customer require ISIA traceability certification.

• Some countries are asking in their import documentation if the serum being imported is ISIA Traceability Certified.

• Trends suggest that the requests by customers to be certified will result in more countries/regulatory agencies deciding to add this qualifier to their import documents.
Status and Continued Improvement of the ISIA Traceability Certification Program

- 85+% of material used in bio-processing applications in the EU, Japan, Australia, New Zealand and USA is currently certified.
- Increased focus from customers and regulators strengthens the program.
- ISIA works to strengthen through program revisions.