



# BSA FRACTION V

BOVINE SERUM ALBUMIN

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## PROLIANT BSA

Proliant is the world's largest and most experienced manufacturer of animal-derived proteins, producing a variety of grades of Fraction V BSA in large volumes with the **highest level of consistency, traceability and quality**. We are the only manufacturer of Bovine Albumin that controls the entire process from collection, through transport and processing. Our **computer-facilitated manufacturing plant** employs a **modern, efficient, closed system** that closely parallels the environmental and process controls found in traditional human albumin manufacturing.

Our commitment to quality also extends well beyond facility and process design. Proliant maintains an extensive Quality Assurance Team that is fully committed to documentation and statistical process control. Standard Operating Procedures are built into every step in the process, from raw material, through processing, packaging, testing and process improvement.

Proliant's traceability and unparalleled attention to excellence in Good Manufacturing Practices ensures that our BSA products meet the exacting standards demanded by diagnostic, biopharmaceutical and research customers worldwide.



## FEATURES & BENEFITS

- + High Purity, Low Interference, Low Background
- + Virtually No Detectable IgG, Endotoxin, Enzyme or Protease Activity
- + Assay Integrity, Component Stability and Cell Culture Suitability
- + Origin Traceability to Facilitate Regulatory Approval
- + Closed Loop Manufacturing - Minimizes Contamination and Maximizes Reproducibility
- + Superior Solubility/Filterability for Ease of Use
- + Responsive Customer/Technical Services
- + Manufactured from USDA-inspected Bovine Plasma (NZ/Australia also available)
- + Manufactured According to FDA Bulk Pharmaceutical Chemical cGMPs
- + **Validated for Clearance of TSE agents**

## BSA PRODUCT INFORMATION

Proliant Bovine Serum Albumin is a high purity Fraction V protein derived from the plasma of USDA-inspected healthy animals from abattoirs located in the United States. The material is initially fractionated by a modified Cohn procedure – a proprietary heat-shock method, and is further isolated from other plasma proteins and lipids by extensive membrane dialysis and filtration. Typical purity levels are in excess of 99%.

For typical analytical results, please see inside cover of this brochure.

// **Protease-free IgG-free and virtually free of contaminants that can result in background interference.**



## REAGENT GRADE

Proliant albumin is also available as an essentially lipid and fatty acid free preparation, with levels of non-esterified fatty acids typically < 0.01% (<0.1mg/g). Proliant Fatty Acid Free BSA is used where the presence of lipids and fatty acids may cause problems, such as hormone and cholesterol assays. Fatty acid free albumin also provides maximum binding sites for the addition of specific fatty acids for cell culture applications.

// **Reagent Grade has the lowest levels of total lipids, fatty acids and free fatty acids of any commercially available albumin.**

QUALITY  
ASSURANCE  
BUILT IN



### COLLECTION

Overseeing and operating the facilities ensures quality from the very beginning.



### TRANSPORT

We exercise complete control over the transport of components to our facilities.



### PROCESSING

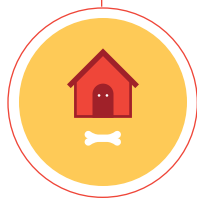
Our modern closed loop system virtually eliminates contaminants for guaranteed purity.

# APPLICATIONS



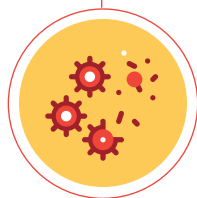
## DIAGNOSTICS

Blocking agent for immunoassays, preventing non-specific binding



## VETERINARY

Increases viral yield during veterinary vaccine and medicine production



## VACCINE

Cultivation of *Leptospira*, *Borrelia* and mycoplasma; virus production



## BIOPHARMACEUTICAL

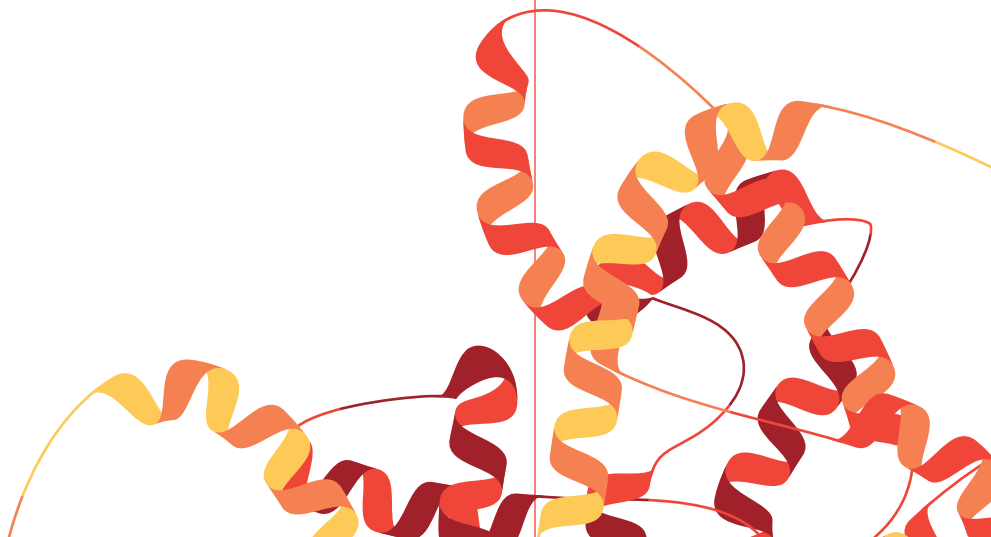
Serum-free and serum-reduced mammalian cell culture/cell preservation



## MEDICAL DEVICE

Component of topical and ex-vivo medical device formulations

// Solubility is outstanding with excellent clarity, filterability and low UV background even at high concentrations.



## DIAGNOSTIC APPLICATIONS

Proliant manufactures several grades of albumin that are ideally suited for sensitive immunodiagnostic and protein chemistry applications, as well as for automated clinical analysis. All lots are protease-free, IgG-free and virtually free of contaminating enzymes, salts, heavy metals and low molecular-weight contaminants that can result in background interference. Solubility is outstanding, with excellent clarity, filterability and low UV background even at high concentrations.

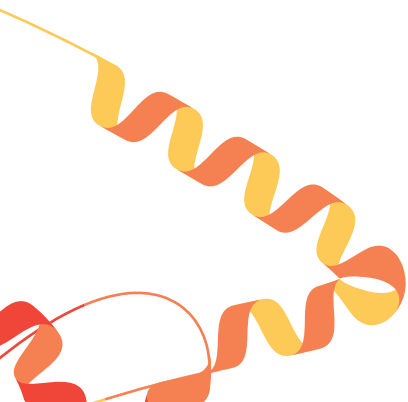
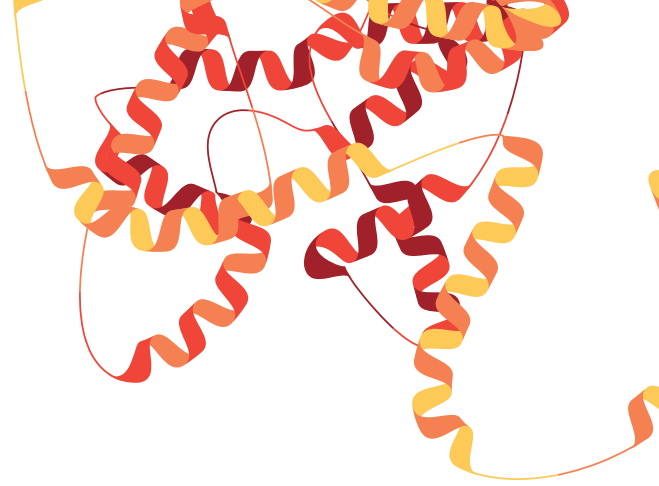
Typical diagnostic applications for Proliant BSA include:

- + **Blocking agent for immunoassays, preventing non-specific binding**
- + **Protein standard, diluent, control**
- + **Protein/Conjugate/antibody stabilization**
- + **Surface coating agent**
- + **Detoxification and inactivation of inhibitory analytes**
- + **PCR optimization/stabilization**
- + **Immunohematology and serology**

## CELL CULTURE, MEDICAL DEVICE APPLICATIONS

Proliant's BSA products are very low in endotoxin, low bioburden, have undetectable amounts of IgG and are highly soluble in media – critical characteristics for veterinary and biopharmaceutical cell culture applications. In addition, our traceability and document trail facilitates our customers' regulatory compliance. Proliant BSA is used successfully worldwide as a component of vaccine, biopharmaceutical and medical device manufacturing. In addition, our Research and Development team will assist our customers in optimizing products to work with customer cell lines and our other serum-free media components, such as transferrin and LiPro™ lipoprotein supplement. Typical applications include:

- + **Serum-free and serum-reduced mammalian cell culture/cell preservation**
- + **Cultivation of Leptospira, Borrelia and mycoplasma; virus production.**
- + **Component of topical and ex-vivo medical device formulations**



# MANUFACTURING

Proliant's proprietary collection system and "Closed Loop" manufacturing process ensure the highest level of control and availability. The material undergoes ante and post-mortem inspections to ensure it is the highest quality edible grade before it is loaded into Proliant owned tankers.

The manufacturing facilities utilize a closed membrane and centrifuge system, ensuring there is no environmental exposure. It is also a computer-assisted process control with 100% stainless steel tanks, piping and is fully Clean In Place (CIP).

From the time our product enters our tankers, to the moment it is loaded into the dryers, the product is never exposed to the external environment.

## BOONE, IA USA

Proliant's state-of-the-art, Bovine Serum Albumin (BSA) production facility, is centrally located in the United States. Spanning 50,000 square feet, including a 10,000 square foot lyophilization suite, allows for extensive production capacity.

Proliant's Boone facility is FDA Bulk Pharmaceutical Chemical GMP's, USDA APHIS Registered and Inspected.

## FEILDING, NEW ZEALAND

Located on the southern portion of the North Island of New Zealand, the facility is essentially a mirror image of the Boone facility, in terms of manufacturing processes and capacity.

## REGULATORY INFORMATION

The manufacturing of BSA by Proliant is designed to ensure that neither the raw material collection, manufacturing process nor the manufacturing environment introduce any contaminants into the product. Installation, Operation and Process Validations have been performed to ensure that equipment and systems function as intended and produce a consistent, reproducible product that will meet established specifications. All SOPs and batch records demonstrating compliance with BPC cGMPs are on file at the manufacturing site and are available for inspection at an audit.

Because of the strong level of control over collection and processing, Proliant has been granted a TSE Certificate of Suitability to the Monographs of the European Pharmacopoeia. Additionally, Proliant is recognized by the International Serum Industry Association as being "Traceability Certified".

# PROLIANT BOVINE SERUM ALBUMIN

TYPICAL ANALYSIS *Please call or email us to discuss specifications*

	Standard Grade pH 7.0 (68100) or pH 5.2 (68500)	Reagent-Grade (Fatty-Acid Free) (68700)	Cohn Analog™ (68300)
Protein	≥ 99%	≥ 99%	≥ 99%
Purity (Albumin)	100%	100%	100%
Moisture	≤ 3%	≤ 3%	≤ 3%
Ash	≤ 2%	≤ 2%	≤ 2%
pH (H <sub>2</sub> O)	6.8–7.2 or 5.0–5.4	6.8–7.2	6.8–7.2
Protease	Not detected*	Not detected*	N/A
Bovine IgG	Not detected	Not detected	Not detected
Endotoxin	<1 EU/mg	<1 EU/mg	<1 EU/mg
Bioburden (APC)	<100 cfu/g	<100 cfu/g	<100 cfu/g
Sodium	6 mg/g	5 mg/g	NA
Potassium	< 1mg/g	< 1mg/g	NA
Chloride	2 mg/g	< 1mg/g	NA
Calcium	< 0.5 mg/g	< 0.3 mg/g	NA
Phosphorus	< 0.3 mg/g	< 0.3 mg/g	NA
Heavy Metals (Pb)	< 1ppm	< 1ppm	NA
NEFA	NA	< 0.01%	NA
Solubility (H <sub>2</sub> O)	Pass	Pass	Pass

*\*Not detected by our methods, sensitivity of 0.0001 units/mg*

*Mycoplasma and virus testing by USDA 9CFR 113.53(c) can be performed on request*



## ABOUT PROLIANT BIOLOGICALS

Proliant Biologicals is part of the Proliant group of companies, leading manufacturers of protein ingredients for food, health, nutrition and biologicals. Founded in 1981, Proliant along with American Protein Corporation, BHJ Corporation and Boyer Valley Corporation are privately held companies of the Lauridsen Group Incorporated. With over \$1 billion in sales and over 50 locations worldwide, The Lauridsen Group serves human, veterinary and industrial applications with high quality, natural source proteins.

Proliant Biologicals manufactures and markets high purity plasma fractions. The company markets products into the diagnostic, veterinary, biopharmaceutical, and nutraceutical and life science research industries.



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