

DIAGNOSTICS CELL CULTURE NUTRITION



PROLIANT HEALTH & BIOLOGICALS

ABOUT US

Proliant Health & Biologicals, founded in 1981, is part of the Lauridsen group of companies, leading manufacturers of protein ingredients for the food, health, nutrition and biologicals industries. With 6 operating companies and 60 manufacturing locations worldwide, the Lauridsen Group serves human, veterinary and industrial applications with high quality, natural source proteins. Proliant Health & Biologicals manufactures and markets high purity plasma fractions and animal extracts for use in the diagnostic, veterinary, biopharmaceutical, nutraceutical and life science research industries.



THE LAB

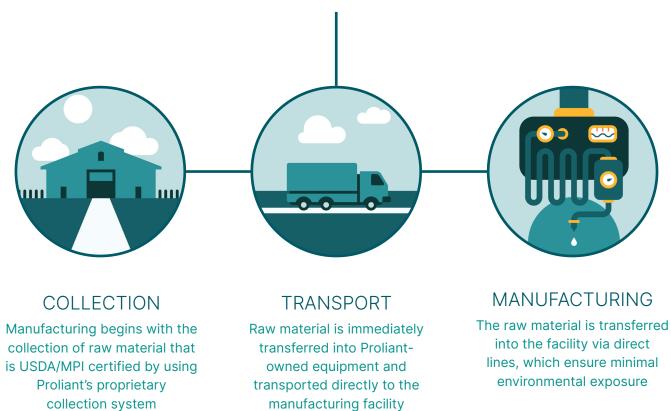
The Lauridsen Advancement Building (L.A.B) is a 21,000 square foot, multifunctional facility. The L.A.B. includes our cell culture lab, research and development laboratories, a fully equipped pilot plant and a research library, located at our headquarters in Ankeny, lowa. Using the facility, scientists and application research experts are responsible for developing and providing innovative solutions for all sectors of pharmaceutical, nutraceutical, biopharmaceutical, vaccine, IVD, and other specialty research markets.

CLOSED-LOOP MANUFACTURING

Proliant's "Closed Loop" manufacturing process means that from the time the raw material enters our tankers or totes, to the moment it is loaded into the dryers, it is never exposed to the external environment.

In addition, Proliant only collects plasma from exclusive abattoirs with our own USDA/MPI approved proprietary collection system. The material undergoes inspections to ensure it is the highest quality before it is loaded directly into Proliant-owned equipment.

Once the raw material reaches our cGMP plant, the material is manufactured through a series of closed tanks, lines, filters, and separation equipment. There are no exposed filter presses or open tanks, nor is any non-food grade or noxious solvent material introduced into the process.



BUILT-IN QUALITY ASSURANCE

MANUFACTURING LOCATIONS

Proliant is the world's largest collector and processor of bovine blood and its derivatives, with unparalleled access to documented sources. Our proprietary, Proliant-owned collection system and our modern, efficient manufacturing process ensures the highest level of control and availability.

BOONE, IOWA

Proliant's state-of-the-art production facility is centrally located in the United States. The facility spans 50,000 square feet, including a 10,000 square foot lyophilization suite, which allows for extensive production capacity. To ensure there is no environmental exposure, the facility utilizes a closed membrane and centrifuge system. It is also computer assisted process control with 100% stainless steel tanks, piping, and is fully clean-inplace (CIP).

With the system that is in place in Boone, Proliant manufactures according to FDA cGMPs and is USDA/APHIS approved as a Technical Blood Facility according to EU Regulations (EC) 1069/2009 and 142/2011, along with receiving an ISO 9001:2015 Certificate.





FEILDING, NEW ZEALAND

The PHB facility in Feilding, New Zealand was constructed to replicate our closed loop manufacturing process which was initially developed and implemented in our Boone facility. The Feilding plant was designed to functionally duplicate the vertically integrated raw material to finished product control used in the US facility and utilizes equipment from the same manufacturers to ensure a truly uniform process.

PRODUCT APPLICATIONS

With over 20 years of experience and the highest quality facilities in the world, we are proud to offer BSA and purified protein products that serve the microbiological, diagnostic, life science, biopharmaceutical, and veterinary vaccine industries worldwide.

| | Caprylate Stabilized pH 7.0 | Caprylate Stabilized pH 5.2 | Fatty-Acid Free | Cohn Analog™ | sBSA | BGG |
|--|-----------------------------------|-----------------------------------|--------------------------|-----------------|-------|-------|
| Application | 68100 (US) 69100 (NZ) | 68500 | 68700 (US) 69760 (NZ) | 68300 | 69115 | 51001 |
| ELISA & RIA (Blocks non-specific binding) | • | • | • | | • | • |
| Western Blot, IHC, IP | • | • | • | | • | • |
| Protein, Enzyme & Conjugate Stabilizer | • | | • | | • | • |
| Chemiluminescent & Flow Cytometry | | | • | | • | • |
| Carrier Protein for Conjugates | | | • | | • | • |
| Primary & Stem Cell Culture | | | • | • | • | |
| Vaccine Production | • | | • | • | • | |

Product Description and SKU

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.



BSA PRODUCTION

The serum is initially fractionated using a proprietary heat-shock method and is further isolated from other plasma proteins and lipids by extensive membrane dialysis and filtration. All lots have undetectable protease, IgG, and are virtually free of contaminating enzymes, endotoxins, salts, heavy metals, and low molecular-weight contaminates that can result in low background interference. As a result of the manufacturing process, our BSA continues to meet and exceed the exacting standards demanded by diagnostic, biopharmaceutical, and research customers worldwide.

| | Caprylate Stabilized pH 7.0 | Caprylate Stabilized pH 5.2 | Fatty-Acid Free | Cohn Analog™ |
|---------------------|-----------------------------------|-----------------------------------|-----------------|-----------------|
| Protein (Dry Basis) | ≥ 98% | ≥ 96% | ≥ 98% | ≥ 96% |
| Purity (Albumin) | ≥ 98% | ≥ 96% | ≥ 98% | ≥ 96% |
| Moisture | ≤ 5.0% | ≤ 5.0% | ≤ 5.0% | ≤ 5.0% |
| pH (10% water) | 6.5 - 7.5 | 5.0 - 5.6 | 6.5 - 7.5 | 6.5 - 7.5 |
| Ash | < 2% | < 3% | < 2% | < 3% |
| Protease | Not Detected | N/A | Not Detected | N/A |
| NEFA | N/A | N/A | < 0.01% | N/A |
| IgG | Not Detected | Not Detected | Not Detected | Not Detected |
| Endotoxin | ≤ 3 EU/mg | N/A | ≤ 3 EU/mg | N/A |

BSA Products | Typical Analysis

Mycoplama and virus testing by USDA 9CFR 113.53(c) [113.46, 113.47] can be performed upon request.



BSA SOLUTIONS

Critical research and manufacturing reagents demand bovine serum albumin that performs at a high level. Proliant BSA solutions are specifically designed to maintain BSA in a natural monomeric state, making it a versatile option for a number of applications. Its consistency, improved blocking uniformity, and increased sensitivity make it a great fit for protein standards, cell culture, vaccine production, and binding and transport applications.



| | Ultra-High Monomer | Azide Preserved | Salt Adjusted | Cholesterol Enhanced | Notes |
|-------------------------|-----------------------|--------------------|------------------|-------------------------|--|
| Caprylate Stabilized | | | | | |
| 68060 | ٠ | • | | | Replacement for Boval CF-10 |
| 68080 | ٠ | • | • | | Replacement for Boval CF-20 |
| 68090 | ٠ | • | | | Replacement for Boval CS-63 |
| Fatty-Acid Free | | | | | |
| 68600 | ٠ | | | | |
| 68610 | | • | | ٠ | Direct replacement for MilliporeSigma MOD-U-CYTE®* |
| 68650 | | • | • | | |

Product Description and SKU

PURIFIED PROTEINS

BOVINE GAMMA GLOBULIN

A key step to assay optimization is preventing non-specific binding of antigens and antibodies to one another and the assay support structures, such as plastic reaction wells.

Proliant's Bovine Gamma Globulin aids in the prevention of non-specific binding, and as a passive blocker to address heterophilic antibodies. To achieve the best results, Bovine Gamma Globulin blocking conditions should be optimized for maximal signal-to-noise ratio and should be tested against appropriate controls.

Bovine Gamma Globulins may be used in many assay formats, either as the sole blocking agent or combined with other common blocking agents.

FEATURES & BENEFITS

- High Purity
- Origin Traceability to Facilitate Regulatory Approval
- Closed Loop Manufacturing Minimizes Contamination and Maximizes Reproducibility

BGG | Typical Analysis

| Physical Appearance | White amorphous flakes |
|---------------------|------------------------|
| Purity | ≥ 96% |
| Protein (Dry Basis) | ≥ 96% |
| Moisture | ≤ 5.0% |
| Sodium | ≤ 10.0 mg/g |
| Chloride | ≤ 24.0 mg/g |
| рН 1%* | 6.8 - 7.2 |

*1% Ig dissolved in 15mM Phosphate Buffer pH 7 at 25°C



ADULT BOVINE SERUM & NEWBORN BOVINE CALF SERUM

The same quality, safety and reliability you've come to expect from Proliant BSA is now available in our New Zealand origin Newborn Calf Serum (NBCS) and Adult Bovine Serum (ABS). Collected and sterile filtered to minimize endotoxin levels, Proliant's NBCS and ABS are fully traceable and eligible for global export. Commonly used in vaccine production, as a cell culture media additive and/or as a diagnostic assay reagent.

| | Adult Serum | | Newborn Calf Serum | |
|------------------------------|-----------------|---------------|--------------------|--|
| Endotoxin | ≤ 10 EU/ml | Total Protein | > 45 g/kg | |
| рН | 6.5 - 8.5 | Endotoxin | ≤ 10 EU/ml | |
| Osmolality | 240-330 mOsm/kg | рН | 6.5 - 8.5 | |
| Haemoglobin | ≤ 50 mg/dL | Osmolality | 240-330 mOsm/kg | |
| Virus Testing | OMAR/9CFR* | Haemoglobin | ≤ 25 mg/dL | |
| *9CFR available upon request | | Virus Testing | OMAR/9CFR* | |

Serums | Typical Analysis

EXTRACTS

Proliant extract powders are derived from cooking bones with adhering meat and serve as a strong source of nutrients for use in microbiological culture media. The extracts are a mixture of peptides, amino acids, organic acids, nucleotide fractions, minerals and vitamins. Proliant products are not exposed to protein hydrolysis, a damaging treatment, allowing our products to provide a number of the nutrients typically eliminated during peptone manufacture. Our products are relied upon for a number of applications.

PRODUCTS AVAILABLE

51201 - Spray-Dried Natural Beef Stock
52662 - Spray-Dried Natural Beef Stock Spinal-Column Free
51228 - Spray-Dried Natural Chicken Stock
52562 - Spray-Dried Natural Premium Pork Stock

FEATURES & BENEFITS

- High Solubility
- Readily Available
- Consistent Protein Concentration
- High Stability
- Bacterial & Viral Reduction
- Highly Cost Effective
- USDA Inspected
- Responsive Customer Service

IMMUNOLIN®

Immunolin[®] is a protein-based (>90%) dietary supplement containing over 50% (w/w) immunoglobulins that helps support digestive function and a healthy mucosal immune system. The protein mixture found in Immunolin is serum-derived bovine immunoglobulin/ protein isolate (SBI) and is manufactured using a tightly-controlled and highly reproducible process at an FDA-inspected facility. Research studies provide evidence that the diversity of immunoglobulins and proteins found in Immunolin are safe and help improve digestive health and nutritional status by decreasing immune activation through mechanisms that involve antigen binding and strengthening gut barrier function.

| | | / |
|----------------------|---------------|---------|
| ATTRIBUTE | SPECIFICATION | TYPICAL |
| Protein (dry basis) | ≥90.0% | 96.0% |
| Purity (as-is basis) | ≥85% | 92% |
| IgG | ≥45% | ≥55% |
| Fat | <0.7% | ≤2.0% |
| Moisture | ≤8% | 4.1% |
| Ash | ≤8% | 1.8% |

Immunolin | Typical Analysis

Supplemental Facts



| | AMT. PER 1 G SERVING |
|----------------------------|----------------------|
| otal Protein | 920 mg |
| Immunoglobulin G | 450 mg ተ |
| aily value not established | |
| Serving size: 1-3 | grams |
| | |



IMMUNOLIN[®] | PROVEN EFFECTIVENESS

The IgG content of SBI has previously been shown to bind to a variety of microbial antigens (e.g., LPS, flagellin, peptidoglycan, etc) associated with gastrointestinal disorders. PHB continues to learn about the broad impact of SBI, studying new, relevant antigens of interest to test for IgG binding. Below is a list of antigenic components that have been shown to bind to IgG, including negative-gram bacteria (*C. albicans, H. pylori*, S. dysenteriae, and E. coli) commonly associated with GI inflammation and disease.

SBI Binds to these Antigens:

- C. albicans lysate
- C. albicans Als3 protein
- H. pylori CagA protein
- Shiga-like toxin type 1
- Lipopolysaccharide (LPS)
- C. difficile Toxin A & B
- Aflatoxion B2
- Aflatoxin G1
- Peptidoglycan
- Flagellin
- E. coli

+24 more common antigens

- Cytolethal distending toxin subunit A
- Cytolethal distending toxin subunit C
- Gliadin
- Zymosan
- C-di-AMP
- Serratia Marcescens
- Salmonella Typhimurium
- Klebsiella Pneumonia
- Staphylococcus
- MDP
- CpG



Immunolin | Typical Amino Acid Profile

| | TYPICAL | | TYPICAL | | TYPICAL |
|---------------|---------|---------------|---------|------------|---------|
| Alanine | 4.4 | Histidine | 2.4 | Proline | 5.8 |
| Arginine | 5.1 | Isoleucine | 3.0 | Serine | 9.0 |
| Aspartic Acid | 9.1 | Leucine | 8.0 | Threonine | 7.8 |
| Cystine | 2.3 | Lysine | 7.0 | Tryptophan | 2.0 |
| Glutamic Acid | 11.1 | Methionine | 1.0 | Tyrosine | 5.2 |
| Glycine | 4.2 | Phenylalanine | 4.5 | Valine | 8.1 |

Analysis of seven separate production lots (July 2012 - April 2013)





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