CHANGE NOTIFICATION

Date: March 1, 2023

From: Daniel Ma, Director of Quality Assurance

Subject: Rebranding | Certificate of Analysis | Lot Number Assignment Plan

Dear Valued Customer:

Proliant Health & Biologicals is committed to providing customers with unmatched service, products, and innovation. We decided to focus on a few internal improvement projects that are aligned with our most recent customer satisfaction survey as part of our continuous improvement process and to dynamically reposition ourselves in this ever-evolving supply chain to become more reliable, innovative, and resourceful.

The biggest change you will see within this year will be our rebranding effort: Proliant Biologicals USA, Proliant New Zealand and Entera Health will rebrand into Proliant Health & Biologicals with a revamped logo, **without any change in the current ownership, manufacture locations or manufacture methods, raw materials/ingredients, regulatory status, finished product quality, batch size or availability.**

Customers located in The People's Republic of China may not receive products with the post-rebranding label and packaging until a later date due to potential delay from updating the GACC registration. Below you will see a link to examples of the new logo, rebranded label template, rebranded letterhead, and an example of the new universal Certificate of Analysis content. Examples of other service documentations, certificates, etc… are available upon request.

The scope of this change notification is limited to **Proliant Biologicals' Certificate of Analysis, Lot Number Assignment Plan, and product labels**. The following changes will be applied to various product families:

1. Adjustment to the format and alignment. **General Proliant Release Specifications will be on the first page unless there are custom specifications in place. Extra tests requested by the customers will be placed on the second page.**
2. Lower the current Endotoxin specification for selected products from ≤3 EU/mg to ≤1 EU/mg without changing the current limulus amoebocyte lysate (LAL) method to maintain consistency.
3. Protease limit for selected products will be adjusted from ≤0.005 units/mg to <0.001 units/mg, the detection limit of our current method. The specification will be "None Detected" with detection limit of 0.001 units/mg listed.

4. Adding our internal release specification for our total aerobic microbial count/bioburden on the CoA for selected products and lowering the **current release specification** of ≤1000 CFU/g to ≤500 CFU/g.
5. The method for our bioburden testing remains the same as plate count/pour plate method while adjusting the test standard to be aligned with the harmonized standard of USP <61>, EP2.6.12, JP 4.05 section I and modified ChP 1105 to eliminate any potential differences in testing standards across the world.
6. The existing Lot Numbering System will be updated to an improved format. **This change will not impact the traceability of the existing products manufactured prior to this change, nor have any impact on the current definition of lot or batch**.
7. Label format will be harmonized between different product lines to have a more unified appearance. Any existing product-specific recommended storage condition will be listed if applicable. The expiration date will be included on the labels based on the current shelf-life information found on our website. Each product family will have a different colored border for better aesthetics.

These changes will better reflect the uniformity of the manufacturing process and the consistent quality of BSA manufactured by Proliant across all locations. An example of the new universal Certificate of Analysis is available via the link below. SKUs impacted by those changes are detailed in Table 1 and the Lot Numbering System is detailed in Table 2 via the link below.

Proliant Health & Biologicals' current target to implement the above changes applies to relevant products manufactured starting on June 1st, 2023. Customers may not see the new branding until July due to the time required for product release tests and shipment process. All products manufactured prior to this date, and not required to be stored below freezing temperature, will be harmonized by the end of 2023, without any change in their existing lot number. These efforts are part of our long-term commitment to continuous improvement as the world's premier manufacturer of proteins supporting human and animal health applications.

Please direct any questions to your Proliant Health & Biologicals Sales Representative or Customer Service Representative. This information is also available on our website here.

Sincerely,

Daniel Ma
Director, Quality Assurance

Logo:

Letterhead:

Label:


Color coded based on product line
PROLIANT
HEALTH & BIOLOGICALS
XXXXXXXXXX
Lot Number: XXXXXXX
SKU: XXXXXXX
Net Weight: XXXXXXX
Manufacturing Date: XXXXXXX
Expiration Date: XXXXXXX
Storage: *If Applicable*
Manufactured by: XXXXXXXXX
www.phb1.com
XXXXXX
Product specific information
XXXXXX
Product specific information
Color coded based on product line

Certificate of Analysis

Date of Manufacture: July 18, 2022
Expiration Date: July 18, 2027
Product Description: **Bovine Serum Albumin**
Standard Grade pH 7.0
Lyophilized Powder
For Research or Further Manufacturing Use Only
Lot Number: **BBB2199101**
SKU Number: **68100**

Analysis:

Analyte	**Specification**	**Result**	**Method**
Appearance	White to yellow with tan to green cast powder	Pass	Visual Inspection
Purity	≥ 98.0%	100.0%	Agarose Gel Electrophoresis
Protein (Dry Basis)	≥ 98.0%	98.4%	Nitrogen Analysis
Moisture	≤ 5.0%	1.2%	Loss on Drying
Ash	< 2%	1.6%	Residue on Ignition
BIgG	None Detected	None Detected	Turbidimetric Analysis
Solubility	Clear to slightly hazy faint yellow to yellow-green solution	Pass	Visual Inspection, 4% in water
Protease	None Detected (<0.001 Units/mg)	None Detected	Enzymatic Assay
pH	6.5 to 7.5	7.1	10% solution in water
Heavy Metals (Pb)	≤ 10 ppm	< 0.50 ppm	ICP
Endotoxin	≤ 1 EU/mg	< 0.1 EU/mg	LAL
Total Microbial Count	≤ 500 CFU/g	< 1 CFU/g	USP<61>, EP2.6.12

During the manufacturing process, the material was subjected to a pH of ≤ 5 and a temperature ≥ 65°C for a minimum of 3 hours and was not commingled with any other material of animal origin.

Name
Quality Department

Date

Certificate of Analysis

Custom Specifications

Date of Manufacture: July 18, 2022
Expiration Date: July 18, 2027
Product Description: **Bovine Serum Albumin**
Standard Grade pH 7.0
Lyophilized Powder
For Research or Further Manufacturing Use Only
Lot Number: **BBB2199101**
SKU Number: **68100**

Analysis:

Analyte	**Specification**	**Result**	**Method**
Mycoplasma	None Detected	None Detected	Culture
Adventitious Viral Agents	None Detected	None Detected	9 CFR 113.53(c) [113.46,113.47]
VSV	None Detected	None Detected	Virus Isolation
BT	None Detected	None Detected	Virus Isolation

Name
Quality Department

Date

Certificate of Analysis

Date of Manufacture: 08 April 2022
Date of Expiry: 08 April 2027
Product Description: **Bovine Serum Albumin**
Standard Grade pH 7.0
Lyophilized Powder
For Research or Further Manufacturing Use Only
Lot Number: **NZB2098101**
SKU Number: **69100**

Analysis:

Analyte	**Specification**	**Result**	**Method**
Appearance	White to yellow with tan to green cast powder	Pass	Visual Inspection
Purity	≥ 98.0%	100.0%	Agarose Gel Electrophoresis
Protein (Dry Basis)	≥ 98.0%	101.2%	Nitrogen Analysis
Moisture	≤ 5.0%	1.2%	Loss on Drying
Ash	< 2%	0.8%	Residue on Ignition
BIgG	None Detected	None Detected	Turbidimetric Analysis
Solubility	Clear to slightly hazy faint yellow to yellow-green solution	Pass	Visual Inspection, 4% in water
Protease	None Detected (<0.001 Units/mg)	None Detected	Enzymatic Assay
pH	6.5 to 7.5	6.9	10% Solution in water
Heavy Metals (Pb)	≤ 10 ppm	< 1 ppm	ICP
Endotoxin	≤ 1 EU/mg	0.017 EU/mg	LAL
Total Microbial Count	≤ 500 CFU/g	< 1 CFU/g	EP2.6.12, ChP 1105

During the manufacturing process, the material was subjected to a pH of ≤ 5 and a temperature ≥ 65°C for a minimum of 3 hours and was not commingled with any other material of animal origin.

Name
Quality Department

Date

Certificate of Analysis

Custom Specifications

Date of Manufacture: 08 April 2022
Date of Expiry: 08 April 2027
Product Description: **Bovine Serum Albumin**
Standard Grade pH 7.0
Lyophilized Powder
For Research or Further Manufacturing Use Only
Lot Number: **NZB2098101**
SKU Number: **69100**

Analysis:

Analyte	**Specification**	**Result**	**Method**
Asepsis	None Detected	None Detected	Culture
BVD Virus	None Detected	None Detected	Virus Isolation
Mycoplasma	None Detected	None Detected	Culture
Pathogen Inducing Cytopathy	None Detected	None Detected	Virus Isolation
Pathogen Inducing Haemadsorption	None Detected	None Detected	Virus Isolation
Sodium	FIO	3.5 mg/g	ICP
Potassium	FIO	<0.004 mg/g	ICP
Calcium	FIO	0.04 mg/g	ICP

Name
Quality Department

Date

Table 1:

SKU #	Product Name	Protease Specification to "None Detected, LoD 0.001 Units/mg"	Bioburden Specification to "≤500 CFU/g"	Endotoxin Specification to "≤ 1 EU/mg"
Lyophilized Powders				
68100	Bovine Serum Albumin Standard Grade pH 7.0 Lyophilized Powder	●	●	●
68101	Bovine Serum Albumin Standard Grade pH 7.0 Lyophilized Powder	●	●	●
68110	Bovine Serum Albumin UltraTech Grade Lyophilized Powder	●	●	●
68300	Bovine Serum Albumin Cohn Analog Culture Grade Lyophilized Powder		●	
68500	Bovine Serum Albumin Standard Grade pH 5.2 Lyophilized Powder		●	
68700	Bovine Serum Albumin Reagent Grade Fatty Acid Free Lyophilized Powder	●	●	●
68701	Bovine Serum Albumin Reagent Grade Fatty Acid Free Lyophilized Powder	●	●	●
68910	Bovine Serum Albumin Biotechnology Grade Lyophilized Powder		●	●
69100	Bovine Serum Albumin Standard Grade pH 7.0 Lyophilized Powder		●	●
69760	Bovine Serum Albumin Precision Grade Fatty Acid Free Lyophilized Powder		●	●
67645	AlbuRich P15 Lyophilized Powder	●		
67675	AlbuRich P140 Lyophilized Powder	●		
67685	AlbuRich PRP Lyophilized Powder	●		
Solutions				
68040	Bovine Serum Albumin Standard Grade 30% Solution	●		
68060	Bovine Serum Albumin Ultra High Monomer Standard Grade 30% Solution, 0.1% Sodium Azide Preserved	●		
68050	Bovine Serum Albumin Ultra High Monomer Standard Grade 30% Solution	●		
68070	Bovine Serum Albumin Standard Grade 30% Solution, 0.1% Sodium Azide Preserved	●		
68630	Bovine Serum Albumin Reagent Grade 30% Solution, Salt Adjusted	●		
68620	Bovine Serum Albumin Reagent Grade 30% Solution, Salt Adjusted, 0.1% Sodium Azide Preserved	●		

Table 2:

Current Lot Numbering System:

US Products

BB	3	001	1	1	01
Plant	Year	Julian Date	Drying Batch	Sequential #	Internal Location

Example: BB30011101

New Zealand Products

NZ	23	-69100-	001
Plant	Year	SKU	Batch #

Example: NZ23-69100-001

New Universal Lot Numbering System

BB	**B**	**3**	**001**	**1**	**01**
Plant	Product Family	Year	Julian Date	Sequential/Batch #	Internal Location

Product Family	Letter Designation	Example
Bovine Serum Albumin & AlbuRich	B	BBB3001101, NZB3001101
Bovine Gamma Globulin	G	BBG3001101, NZG3001101
Adult Bovine Serum	A	BBA3001101, NZA3001101
Newborn Bovine Serum	N	BBN3001101, NZN3001101
Raw Plasma	P	BBP3001101, NZP3001101