

CERTIFICATE OF ANALYSIS

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Product Name:	LACTOBACILLUS & BIFIDUS FOR BREAST FED BABIES		
Customer:	PROVEN PROBIOTICS	Product Code(s):	PROVEN-001-6-F
Formulation Version	V6.0	Batch Number:	67357
Date of Manufacture:	APRIL 2024	Expiry Date:	APRIL 2026

Product has been manufactured in accordance with the Product Formulation and Release Specification (PFRS). Please see copy of PFRS for details.

Test	Method ¹	Acceptance Criteria	Result
Physical Analysis			
Appearance ²	SOP 232 OP6 Cultech	Cream Free Flowing Powder with Small Granules	Conforms
Average Fill Weight	SOP 232 OP6 Cultech	Bottle contents 6g ± 7.5% (5.55g to 6.45g)	6g
Uniformity of Weight	USP <2091> Cultech	Complies with USP<2091>	Conforms
Active Ingredient Analysis			
Total Lactic Acid Bacteria Count	SOP 476 OP6/QBI ³ Cultech	≥10 Billion CFU/serving	15 Billion CFU/serving
Microbial Analysis			
Total Yeast and Mould	M022 Intertek	≤1 x 10 ² CFU/g	<20cfu/g
<i>Enterobacteriaceae</i>	M009 Intertek	≤1 x 10 ² CFU/g	<10cfu/g
<i>Escherichia coli</i>	M011 Intertek	*Absent in 1g	Absent
<i>Salmonella</i>	M040 Intertek	*Absent in 10g	Absent
<i>Staphylococcus aureus</i>	M013 Intertek	*Absent in 1g	Absent

¹Or other validated internal Cultech or External Laboratory method

²Naturally sourced ingredients vary in both physical and organoleptic properties, consequently the appearance of products containing these may vary from batch to batch.

³Method suitability to be confirmed on first 5 batches of product – additional method development might be required for this specific combination of ingredients. Product may be released QBI during the validation period. At the end of 5 production runs the methods will be updated to move to (a) Analytical Test only, or (2) QBI only or (3) Formulation reviewed to increase overage to allow analytical testing.

*Absent means <1 x 10¹

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Test	Method ¹	Acceptance Criteria	Result
Allergen Testing			
Gluten ⁴	SOP 104 OP6 ELISA Cultech	≤20ppm	<5 ppm
Total Milk ⁴	SOP 106 OP6 ELISA Cultech	Not Detected (<MDL**)	<2.5ppm
Lactose ⁴	SOP 105 OP6 Enzymatic Cultech	Not Detected (<MDL**)	<100ppm

⁴Fully analysed on first three batches for validation. Then move to analysis on a skip lot (every fifth) batch basis.

**MDL Method Detection Limit (Total Milk <2.5ppm, Lactose <100ppm)

Created By:	KARYS RAYNER
Position:	QC TECHNICIAN
Signature:	
Date:	26/04/2024

On behalf of the Quality Manager, Cultech Ltd

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