

# STATE-OF-THE-ART

## Testing, Screening, and Standardised Production Process



From donor to recipient, the entire lifecycle of Prolacta's human milk-based nutritional products follows a standardised quality and safety production process. These industry-leading procedures are modelled after those used in the human plasma and blood industries, which surpass food-product safety standards. Hospitals choose Prolacta's nutritional products, which are processed in a pharmaceutical-grade facility, to protect the health and well-being of the most fragile patients.

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## 1 MEDICAL REVIEW

- Donor undergoes medical and social screening
- Donor must produce milk in excess of what her baby needs and provide written Confirmation of Health from her doctor and her baby's paediatrician

## 2 BLOOD TESTING AND DNA SAMPLE

- Donor is tested for HIV-1 & 2, HTLV-I & II, HBV, HCV, and syphilis
- DNA sample is taken to create a genetic ID of the donor so breastmilk can be verified (no genetic information is retained)



## 3 BREASTMILK SHIPMENT TO PROLACTA

- Donor's freezer temperature is verified
- Donor is supplied with storage bags, freezer bricks, an insulated cooler, and a prepaid shipping label
- Donor ships frozen breastmilk to Prolacta

## 4 RAW MILK TESTING

- Prolacta developed, validated, and implemented more than 20 tests for screening raw milk to ensure quality and safety
- DNA matching is performed for assured donor identification; raw milk is visually inspected and tested for *Bacillus cereus* (*B. cereus*), adulteration, nicotine, and drugs of abuse
- Raw milk is directly tested using a nucleic acid amplification test (NAAT) for disease-causing pathogens, including:
  - Human immunodeficiency virus type 1 and type 2 (HIV-1, HIV-2)
  - Human T-cell lymphotropic virus type I and type II (HTLV-I, HTLV-II)
  - Hepatitis virus B and C (HBV, HCV)
  - SARS-CoV-2 (COVID-19)
  - Zika virus (ZIKV)
  - Treponema pallidum* (syphilis)
  - Mycobacterium tuberculosis* (TB)

## 5 PROCESSING AND PASTEURISATION

- Microbiological testing is done at multiple points in the process
- Donor breastmilk is formulated into fortifier or standardised human milk products, then pasteurised with a vat method following time and temperature profiles defined by the U.S. Food and Drug Administration (FDA) in its Pasteurized Milk Ordinance (PMO)
- Prolacta's vat pasteurisation—a process similar to Holder pasteurisation<sup>1,2</sup>—effectively destroys pathogenic bacteria while retaining high levels of product nutrients
- Nutritional products manufactured with Prolacta's processes preserve the bioactivity of human milk and are clinically shown to improve health outcomes in very low birth weight (VLBW) premature infants such as reduced incidence of bronchopulmonary dysplasia, late-onset sepsis, retinopathy of prematurity, and necrotising enterocolitis when used as part of an exclusive human milk diet in the neonatal intensive care unit<sup>3-8</sup>

## 6 FILLING AND PACKAGING

- Product is filled into high-density polyethylene bottles (BPA free)
- Product is labelled with nutritional values, "use by" date, and product lot number
- Color-specific labelling also provides instructions for safe storage, mixing, and administration



## 7 FINAL PRODUCT TESTING AND FREEZING

- Microbiological screening is conducted, including aerobic count, *B. cereus*, *Escherichia coli*/coliform, *Salmonella*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, yeast, and mould
- *B. cereus* emetic toxin analysis is performed
- Nutritional analysis is performed
- Product is frozen for storage

## 8 QUALITY REVIEW

- Product is not released until all data are reviewed, verified, and approved by Quality Assurance
- Final verification is performed against product specifications to assure product quality

## 9 SHIPPING

- Order is verified to ensure the accurate number of products are packaged
- Frozen products are shipped in insulated coolers with dry ice
- Products are closely tracked until arrival at hospitals
- Coolers are returned to Prolacta, cleaned, and reused to minimize waste

Learn more at [Prolacta.com/safety](https://Prolacta.com/safety)

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