

# Prolacta's Donor Qualification Process



Prolacta Bioscience maintains the highest quality and safety standards in the human milk industry to protect the medically fragile infants we serve.

## We Ensure Donors' Own Children Are Fed First

Prolacta requires a Confirmation of Health certificate from both the mother's physician and her baby's pediatrician stating that both mom and baby are healthy and mom's own infant is well-nourished. This ensures the health and well-being of both mom and baby will not be negatively impacted by breast milk donation.

Prolacta requires that the donors' infant is fed 100% mother's milk until they are 6 months of age, unless there is a medical reason preventing breastfeeding.

This ensures that Prolacta donors have a surplus of breast milk beyond what their own children can consume.

## Committed to the Highest Quality & Safety Standards

Because their excess breast milk will nourish medically fragile infants, Prolacta donors must meet stringent safety standards to donate.

1. Moms interested in donating their extra breastmilk begin the qualification process with an extensive online medical and lifestyle questionnaire.
2. Each mom must present a Confirmation of Health certificate from their physician confirming she is healthy, and confirmation from her baby's pediatrician stating whether the baby is exclusively fed mothers' milk. If the baby is less than 6 months old, the form must indicate that the baby is exclusively receiving mothers' milk for the mom to be eligible.
3. Moms who pass the questionnaire undergo blood tests for:
  - Human immunodeficiency virus (HIV) type 1 and type 2
  - Human T-lymphotropic virus (HTLV) type I and II
  - Hepatitis B (HBV), hepatitis C (HCV)
  - Syphilis
4. Moms then submit a DNA sample (cheek swab) that is used to create a unique donor profile and genetic breast milk ID so the breast milk can be matched to the qualified donor. A DNA sample is taken to create a genetic ID for the sole purpose of verifying the breast milk comes from that qualified donor.
5. The mom's freezer temperature is verified to ensure safety.

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### Once a mom is qualified to donate:

- Donor moms undergo extensive education on important safety measures on breast milk storage, cleaning, sanitizing and storing their pump parts and bottles, and proper milk handling and safety.
- Prolacta supplies donor moms with breast milk storage bags.
- Once ready to ship their breast milk, donor moms are supplied an insulated and reusable cooler with freezer bricks and a prepaid overnight return shipping label.

### Ensuring the Safety of Donated Breast Milk

#### Once the breast milk is received at Prolacta:

Each individual shipment of donor breast milk is pooled and tested. Prolacta developed, validated, and implemented more than 20 tests for screening raw milk to ensure quality and safety. The DNA of each shipment is matched to the qualified donor. Each shipment is tested for dilution, adulteration, 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)

### Milk Formulation and Pasteurization

Donor breast milk is then formulated into fortifier or standardized human milk products, and vat pasteurized using profiles defined by the U.S. Food and Drug Administration (FDA) to ensure pathogen inactivation and the highest level of safety while retaining as much of the natural bioactivity of the milk as possible.<sup>1</sup> Bioactivity is thought to support infants' immunity, development, growth, and long-term health.<sup>2</sup>

### Packaging, Testing, Freezing & Quality Check

Once complete, products go through packaging, final testing, freezing, and quality reviews.

### Shipping to Hospital Customers

Finally, Prolacta's nutritional products are shipped to hospitals worldwide to give critically ill, premature infants the opportunity to benefit from a 100% breast milk-based diet.

#### References:

**1** Data on File **2** Gila-Diaz A, Arribas SM, Algara A, Martín-Cabrejas MA, López de Pablo Ál, Sáenz de Pipaón M, Ramiro-Cortijo D. A review of bioactive factors in human breastmilk: a focus on prematurity. *Nutrients*. 2019;11(6):1307. doi:10.3390/nu1106130