



# Milkin' Mamas Breast Milk Donations

All milk donated through Milkin' Mamas goes to Prolacta Bioscience. Prolacta's proprietary methods for the standardization of human milk provide the highest level of product safety and quality. Consistent with their commitment to make a meaningful difference in the lives of the most vulnerable infants, Prolacta has developed industry leading safeguards that exceed current industry standards, to provide the best product possible.

## Pillars of Quality

From donor to recipient, the life cycle of Prolacta's human milk formulations consists of donor screening; specific testing/safety measures; processing and pasteurization; filling; final product testing; labeling and packaging; quality review and shipping.

### A. Donor Screening

Breast milk donors follow a rigorous screening process based on the blood banking model. Prolacta is the only organization that uses these combined safety steps:

1. Similar to the blood donor industry, potential donors are screened through a medical history survey. After the screening, the donor is entered into Prolacta's proprietary database and assigned a donor number.
2. Once the potential donor passes the medical history survey, she must obtain written approval from her physician and her baby's pediatrician before she can continue in the donation process.
3. The potential donor measures the temperature in her freezer with a thermometer provided by Prolacta. The temperature must be cold enough to store human milk or, unfortunately, the potential donor may not donate.
4. A blood test and a DNA cheek swab are conducted. The blood test screens for several infectious agents including HIV 1&2, HTLV I&II, HBV, HCV, and syphilis. The DNA cheek swab is used to create a donor DNA ID. This DNA ID will be used later to ensure the milk received is from the donor that was blood tested.
5. If the potential donor passes the screening and meets all of the requirements outlined above, she is qualified to be a breast milk donor for a four month period. After four months, if she wishes to continue donating, she must complete a new medical history survey and take another blood test.

### B. Specific Testing / Safety Measures

Incoming donated milk is quarantined until acceptance testing is complete, including the following:

1. The DNA in the donated milk is matched to the donor's DNA ID to assure the milk comes from the donor that was blood tested.
2. Donated milk is subjected to drugs of abuse screening.
3. Each shipment of milk is screened for *Bacillus cereus*, a pathogenic bacterium that cannot be removed through pasteurization.



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## C. Processing and Pasteurization

1. All processing of milk is done in a clean room environment, similar to the biologics industry.
2. At the start of the production process, the milk goes through the following testing:
  - a. PCR testing for the presence of HIV-1, HBV, and HCV.
  - b. Full microbiological panel including Aerobic count, *B. cereus*, *Escherichia coli*, *Salmonella*, *Pseudomonas*, *coliforms*, *Staphylococcus aureus*, yeast and mold.
  - c. Bovine protein testing.
3. Donor milk is formulated into fortifier and standardized human milk product to meet specific protein, fat and calorie specifications.
4. Each production lot is pasteurized following guidance set by the FDA's Pasteurized Milk Ordinance.

## D. Filling

1. Product is filled into polypropylene or high density polyethylene bottles (both BPA free) and frozen.
2. The bottles are weighed to ensure that the intended volume is filled into the bottle.

## E. Final Product Testing

Product is quarantined until all data are reviewed, verified, and approved by Quality Assurance.

1. Full microbiological panel including Aerobic count, *B. cereus*, *E. coli*, *Salmonella*, *Pseudomonas aeruginosa*, *coliforms*, *Staphylococcus aureus*, yeast and mold.
2. Full nutritional analysis is performed.

## F. Labeling and Packaging

1. Product is labeled with lot specific nutritional values, "use by" date, and product lot number.
2. Color specific labeling for safe storage, mixing, and administration.

## G. Quality Review

1. Final verification against product specifications for quality assurance.

## H. Shipping

1. Frozen product is shipped to hospitals in insulated coolers, packed with dry ice.