

Donor Milk Safety: Prolacta's Screening, Testing & Manufacturing Process

Prolacta Bioscience® leads the industry in quality and safety for donor milk screening, testing and processing. With an accomplished scientific team from the human blood plasma industry, Prolacta has modeled its stringent safety criteria for breast milk donation on that for plasma and blood.

Donor Qualification and Screening

- Prolacta's donor process begins with a medical and social questionnaire of all potential breast milk donors.
- Prolacta then obtains a Confirmation of Health from both the mother's physician and from her baby's pediatrician.
- Donors who pass the screening undergo a blood test for HIV-1 & 2, HTLV I & II, Hepatitis B (HBV), Hepatitis C (HBC) and Syphilis, with a combination of serological and nucleic acid (PCR) tests.
- Donors also submit a DNA sample (cheek swab) that is used to create a unique donor profile.

DNA Matching

- Prolacta is the only company that can identify exactly whose milk is in its products and the first in the industry to take this quality and safety measure. When donated milk arrives at Prolacta, testing begins by matching the DNA profile of the milk to the DNA profile obtained during donor qualification.

Milk Testing Unique to Prolacta

- Prolacta has developed, validated and implemented more than 12 tests for the screening of donor milk to ensure quality and safety.
- Drug Testing: An added safety measure unique to Prolacta Bioscience is that all donor milk received also undergoes validated screening for nicotine and marijuana, as well as drugs of abuse such as opiates and other substances.
- Adulteration Testing: The donor milk undergoes multiple tests for adulteration and dilution.
- DNA Matching: Breast milk is matched to donors using proprietary DNA matching technology, which creates a DNA fingerprint of each donor's milk – an essential step that ensures all donor milk comes from women who have been tested and approved.
- Donor milk found to be contaminated is rejected, and the donor is permanently barred from future donation.

Processing and Pasteurization

- Viral Testing: Prolacta is also the only company to perform viral screening using PCR testing for the presence of HIV-1, HBV and HCV.
- Screened and accepted milk is stored in Prolacta's pharmaceutical-grade freezers until it is processed. Prolacta houses the world's largest human milk freezer, capable of holding more than 110,000 L of donor breast milk at an average temperature of -26°C.
- During processing, qualified donor milk from approved donors is pooled and blended in large stainless steel tanks. All donor milk processing is done at Prolacta's pharmaceutical-grade manufacturing facility in ISO 7 and ISO 8 clean rooms.
- Prolacta's products are tested for bacterial contamination at multiple points in the process. The company also conducts environmental monitoring of its cleanroom manufacturing area to ensure the effectiveness of its contamination controls.

Prolacta's Patented Fortifier Process

- The fortifier manufacturing process begins by separating the milk into skim and cream. Once separated, the skim milk is concentrated to the target protein level. Some of the separated cream is then added back to achieve the proper caloric level. Then small amounts of minerals are added, so that when the final product is mixed in the neonatal intensive care unit, the mineral content will meet the guidelines published in the Pediatric Nutrition Handbook.
- The concentrated human milk fortifier is then pasteurized to ensure the highest quality and safety.
- Prolacta uses time/temperature profiles defined by the US FDA in its Pasteurized Milk Ordinance (PMO) to ensure destruction of pathogenic bacteria. These time/temperature profiles have been used in both the dairy industry and human milk banking industry for decades.
 - Prolacta has validated the pathogen reduction capability of its pasteurization process by the same methods used in the biologics industry. This validation demonstrates that Prolacta's pasteurization provides appropriate bacterial and viral log reduction.
 - While there are a number of pasteurization and commercial sterilization processes available, the tremendous health benefits of an exclusive human milk diet in the preterm infant have been demonstrated in human clinical trials solely using Prolacta's patented products and process. There is no clinical data showing similar results using milk pasteurized by any other method.

Final Product Testing/Quality Review

- After filling in BPA-free polyethylene bottles, samples are selected from the beginning, middle and end of the fill for final testing, and the remainder of the lot is quarantined in a freezer until the test results are complete.
- The selected samples go through final microbiological testing for aerobic count, *B. cereus*, *E. coli* and coliforms, Salmonella, Pseudomonas, *S. aureus*, yeast and mold.
- Finally, a full nutritional analysis using wet chemistry tests is performed, which is used to create FDA-compliant labels.
- When the testing data and manufacturing records have been reviewed and verified by Prolacta's Quality Assurance team, the lot is approved and released for labeling with specific lot nutritional values, use-by date and lot number.