

# State-of-the-art testing, screening, and standardized production process

## Medical Review

### Medical Review

- Donor undergoes medical and social screening
- Donor must provide written approval from her doctor and her baby's pediatrician

## Blood Testing and DNA Sample

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- Donor is tested for human immunodeficiency virus type 1 and type 2 (HIV-1/HIV-2), human T-lymphotropic virus type I and type II (HTLV-I/HTLV-II), hepatitis virus type B (HBV) and type C (HCV), and syphilis.
- DNA sample is taken to create genetic profile of the donor so milk can be verified once received at Prolacta Bioscience, Inc.

## Donor Milk Shipment to Prolacta

### Donor Milk Shipment to Prolacta Bioscience®

- Donor is supplied with storage bags, freezer bricks, an insulated cooler, and a prepaid FedEx shipping label
- Donor ships frozen milk to Prolacta

## Raw Milk Testing

### Raw Milk Testing

- DNA matching is performed for assured donor identification; milk is tested for *B. cereus* and for adulteration, nicotine, and drugs of abuse
- Each donation is tested using nucleic acids amplification testing (NAT) for pathogenic viruses and bacteria listed below:
  - HIV-1/HIV-2
  - HTLV-I/HTLV-II
  - HBV/HCV
  - Zika virus (ZIKV)
  - *Treponema pallidum*
  - *Mycobacterium tuberculosis*

## Processing and Pasteurization

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- Microbiological testing is done at multiple points in the process
- Donor milk is formulated into fortifier or standardized human milk products, then pasteurized following the standards of the Pasteurized Milk Ordinance set by the FDA

## Filling

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- Product is filled into high-density polyethylene bottles (BPA free) and is then frozen

## Final Product Testing

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- Microbiological screening is conducted: aerobic count, *B. cereus*, *E. coli*, *Salmonella*, *Pseudomonas*, coliforms, *S. aureus*, yeast, and mold
- Full nutritional analysis is performed

## Labeling and Packaging

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

## Quality Review

### Quality Review

- Product is quarantined until all data are reviewed, verified, and approved by Quality Assurance
- Final verification is performed against product specifications to assure product quality
- Frozen product is shipped to hospitals in insulated coolers with dry ice

## Shipping

To provide your preterm patient with a 100% human milk-based diet, call: 1-888-PROLACT (1-888-776-5228) or visit [www.prolacta.com](http://www.prolacta.com)