

Human milk is critical for improving health outcomes for infants, especially those born preterm. For more than 100 years, nonprofit donor human milk banks have safely screened and processed human milk.

Highlights

- 2017 research shows Holder pasteurization, used by Mothers' Milk Bank, preserves more of the unique immune factors and nutrients of donor human milk than retort processing, which is used by commercial companies.
- The cost of milk from a nonprofit milk bank costs \$4 per ounce and for-profit banks charge from \$5.50 to \$16.00 per ounce.
- Increased capacity of nonprofit milk banks assure availability of human milk.

**Nonprofit banks using Holder pasteurization
MMB and other HMBANA affiliates**

**For profit companies using retort
processing such as Medolac**

Donor Screening

Follow HMBANA guidelines for the establishment and operation of a donor human milk bank. All banks are registered by the FDA. Detailed verbal and written screening by trained donor relations personnel including lactation and medical history.	Unreported
Mother fills out a detailed medical history form. Detailed instructions on clean collection procedures and containers provided to mother.	Mother fills out a detailed medical history questionnaire.
Healthcare provider provides information on Hepatitis, TB, herpes history, transfusion history and medications. Signed forms from maternal doctor and pediatrician of infant.	Unreported
Blood is drawn and tested at an accredited lab such as Quest Laboratories or American Red Cross National Testing Laboratories for the following: Hepatitis B Surface Antigen, Hepatitis C Antibody Screening, HIV types 1 and 2 Antigen and Antibody Screening, Human T-lymphotropic Virus types 1 and 2 Antibody Screening, and RPR (syphilis) Antibody Screening. Confirmatory testing is performed as necessary. CMV and WNV are both killed by pasteurization. Exotic parasites are ruled out through a detailed travel history of the donor or tested for if unable to rule out.	Labcorp draws blood, which is tested at American Red Cross National Testing Laboratories for the following: Hepatitis B Surface Antigen and Antibody Screening, HIV types 1 and 2 Antigen and Antibody Screening, Human T-lymphotropic Virus types 1 and 2 Antibody Screening, RPR (syphilis) Antibody Screening, WNV NAT, CMV Antibody, Chagas, and T. cruzi screening.
Indeterminate results reviewed by medical director.	Repeat blood test every 6 months. False positives follow the recommendation of infectious disease physician.
Depots or donation and outreach centers collect milk in their communities.	Unreported
Nonprofit milk banks have been providing donor human milk to hospitals and outpatients for more than 100 years. HMBANA banks dispensed 5 million ounces in 2016. \$4 per ounce processing fee (MMB Colorado)	Company founded 2009, opened 2014, accountable to stock holders. Reports 1.5 million ounces dispensed. Price not published. Some report \$5.50 to \$16.00 per ounce.

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Donor Qualifications

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No use of tobacco or nicotine products, illicit drugs or marijuana. Medication use must be approved prior to donation. Mega dose vitamins and/or herbal products are not acceptable.	Donors 'own' the Co-op and sign a member agreement of no alcohol use or no drug use. Medication use must be approved prior to donation. Mega dose vitamins and/or herbal products are not acceptable.
Waiting periods for donors who have received blood products in past 6 months, for transplant recipients, body piercings and tattoos, or intimate contact with anyone at risk for HIV within last 12 months.	Unreported
No donations after infant turns 18 months.	Unreported
Donors are not paid, eliminating any incentive to supply false information or augment milk volumes.	100 oz are donated before qualifying for payment of \$1/oz, thereafter. Payment 90 days after donation. Donors must pass all tests before payment.
Many banks separate milk from donors with preterm infants, colostrum and milk from those with no dairy products in their diet. Milk pooled in small volumes for quality assurance.	The milk purchased includes milk from mothers of preterm babies as well as mothers of full term and older babies. The milk is pooled in very large volumes.

Milk Processing

Milk Processing

Milk pooled from 2-8 donors, Holder pasteurized and then frozen. Microbiological testing and must have no bacterial or fungal growth. Nutritional analysis is optional and many banks do including MMB of Colorado. Foss FT 120, Calais and other analyzers used. Nutrition is reported to customers. Drug testing is not required by HMBANA. MMB Colorado tests for amphetamines, cocaine, THC, opiates, and phencyclidine. Testing since October 2015 with no positive drug results. Levels of heavy metals are insignificant. Peer-reviewed research does not support screening.	Microbiological testing: Milk tested for: APC, S. aureus, E. coli and coliforms, yeasts and molds, Enterobacteriaceae, Adulteration w/ water or any other type of milk, pH and osmolality, Nutritional analysis: Mid-infrared Human Milk Analyzer (Calais HMA). Third party lab tests for ethanol, heavy metals, drugs of abuse: amphetamines, cocaine, cannabinoids, opiates, phencyclidine, methadone and barbiturates.
Milk pooled in relatively small volumes of several hundred ounces. Handled by trained lab techs.	Milk pooled in a minimum of 1,000 gallons with ~200 donors per lot.
Holder pasteurization heats milk to 62.5 degrees C. The process has been researched extensively. This process preserves donor milk's nutritional value. Lysozyme, secretory IgA, oligosaccharides are retained. Fat and protein stable. <i>Containers:</i> Many banks use plastic bottles and caps and two banks, including MMB Colorado, use glass bottles and metal caps to prevent any leaching of chemicals in milk during heating.	Retort process heats milk to 121 degrees C, twice as hot as Holder, and uses 15 lbs of pressure. The retort pasteurization method creates a commercially sterile product, eliminating all bacteria, virus and spores along with elimination or severe reduction in nutrients including lysozyme, secretory IgA, and oligosaccharides.
Nonfat milk processed in lab for babies with chylothorax.	Unreported

Product

Product

Arrives frozen. HMBANA guidelines set donor milk expiration at one year from pump date. Expires 48 hours after thawing, if refrigerated. Banks work with hospitals to ensure expiration dates fit needs. Decades of peer-reviewed research supporting positive outcomes for fragile NICU infants.	Arrives in plastic pouch at room temperature. Nutrition label provided reporting macronutrients. Stored at room temperature for up to 3 years. Expires 7 days after opening, if refrigerated. No published research on outcomes.
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Disclaimer: Information pertaining to Medolac is drawn from available materials and resources. RMCHF assumes no liability for errors or omissions.

References:

1. Ewaschuk, JB et al. (2011) Effect of pasteurization on selected immune components of donated human breast milk. J of Perinatal, 31(9):593-598.
2. Peila, C. et al. (2017) Human milk processing: A systematic review of innovative techniques to ensure the safety and quality of donor milk. JPGN, 64(3), 353-361.
3. Meredith-Dennis, L. et al. (2017) Composition and variation of macronutrients, immune proteins, and human milk oligosaccharides in human milk from nonprofit and commercial milk banks. J Human Lact, doi: 10.1177/0890334417710635
4. Lima, H. et al. (2017) Bacteria and bioactivity in Holder pasteurized and shelf-stable human milk products. Curr Dev Nutr, doi: https://doi.org/10.3945/cdn.117.001438.

<https://www.ncbi.nlm.nih.gov/pubmed/28614672>
<http://cdn.nutrition.org/content/early/2017/08/02/cdn.117.001438>