

Ensuring safety and quality

Human milk banks use rigorous quality assurance practices to protect infants

Ensuring the safety and quality of donor milk is the top priority of human milk banks. In South Africa, all milk banks have access to a rigorous set of quality assurance practices established by the Human Milk Banking Association of South Africa (www.hmbasa.org.za) to safeguard the health of vulnerable infants. Compliance with standardized operating procedures creates confidence in the system and encourages greater participation.

SCREENING DONORS TO REDUCE RISK

Donor screening and selection is a first step toward ensuring the safety of the human milk banking process (Figure 1). Donors must be in good health and should not have any high-risk lifestyle behaviors. Women who want to donate are tested for HIV, syphilis, hepatitis B, and other infectious diseases. Those testing positive are not allowed to donate. If a woman is donating for more than three months, the HIV test needs to be repeated. Women who obtained piercings, tattooing, or traditional scarification in the preceding 12 months cannot participate. Donors must be nonsmokers, must limit alcohol intake in the 24 hours before donation, and must avoid taking any medications that are contraindicated with breastfeeding.

ENSURING SAFE HANDLING IN DONORS' HOMES

Approved donors must follow rigorous safety measures for handling and storing breastmilk at home. They receive detailed training on appropriate hygiene, including hand-washing and sterilization of breast pumps and



Brazilian National Network of Human Milk Banks

containers. For collecting breastmilk, they must use glass jars or hard plastic containers that are deemed to be safe. Donors must have properly working freezers for immediately freezing milk after it is expressed or pumped. The milk must be transported to the milk bank via secure cool boxes packed with ice packs.

MEETING PASTEURIZATION STANDARDS

Pasteurization is a key step in maintaining high-quality processing of breastmilk. Breastmilk from donors must be kept frozen until it is pasteurized, usually within two weeks of collection. It also needs to be processed under hygienic conditions, which means staff must use proper hand-washing techniques and sterile gloves.

Figure 1. Process to ensure the safety and quality of donor milk.

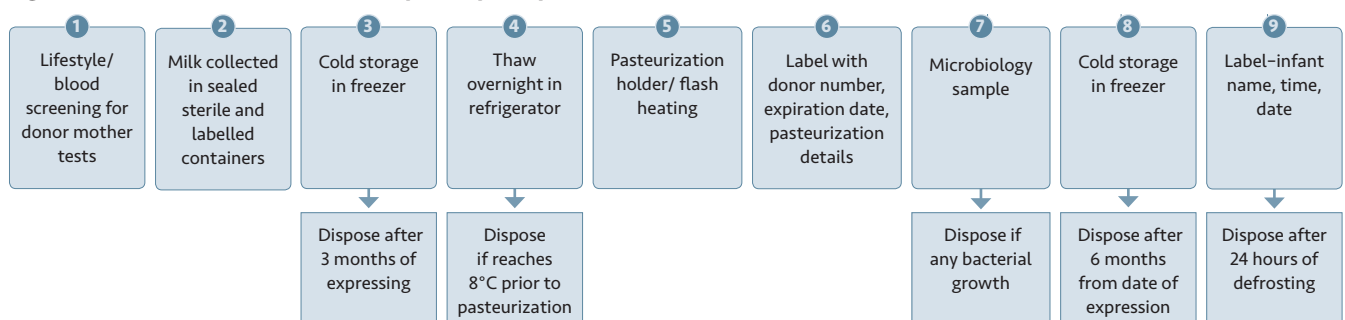


Table 1. Effects of two types of pasteurization on key human milk components (% retention)

Milk component	Method	
	Holder pasteurization	Flash-heating
Lactoferrin <i>iron-binding protein that has antimicrobial and antiviral properties</i>	44%	100%
Immunoglobulin A <i>major antibody that protects against pathogens</i>	80–100%	80%
Lysozyme <i>enzyme with antimicrobial properties</i>	75–100%	74%
Thiamine, folic acid <i>vitamins important for neurological development</i>	100%	100%

Sources: Lawrence and Lawrence, 2005; Chantry et al., 2010; Chantry et al., 2009; Israel-Ballard et al., 2008.^{1–4}

Pasteurization involves heating milk to specified temperatures, which kills potential pathogens while maintaining most of the milk's immunological and nutritional benefits. Several types of pasteurization are used for treating breastmilk. One is the Holder method, which uses a commercial-grade pasteurizer to heat milk to 62.5°C for 30 minutes. Another method is flash-heating, in which milk is rapidly heated to approximately 72°C by heating milk-filled glass jars in a bath of boiling water. Table 1 shows that both methods effectively preserve most of the milk's immunological and nutritional benefits.

SAFEGUARDING QUALITY AT THE MILK BANK

Post-pasteurization procedures are important to safeguard the quality of donor milk before it is consumed. Sterile technique is maintained throughout processing. Confidential records need to be kept for five years to track donor medical history. In addition, donor breastmilk samples are labeled with the donor number, date of collection, and pasteurization batch number and date. Batch samples of donor breastmilk are tested regularly after pasteurization, and milk showing bacterial growth is discarded.

Donor pasteurized milk can be stored at –18°C for up to six months. For pre-term infants, breastmilk should be stored for only three months. Thawed milk can be stored for up to 24 hours in a refrigerator prior to use.

TRAINING STAFF FOR OPTIMAL RESULTS

Human milk banks are managed by highly trained personnel, including a medical director, neonatologists, lactation consultants, and microbiologists. Staff receive ongoing training in a range of topics, such as how to validate, calibrate, and inspect milk processing equipment.

MAINTAINING STANDARDS WHILE SCALING UP EFFORTS

Human milk banks in South Africa operate on a small scale. They are unable to meet the needs of all infants who could benefit from these banks. Additional human milk banks are necessary and should be distributed equitably throughout the country.

Quality assurance must be maintained while expanding the availability of milk banking programs. Safety cannot be compromised. National-level leadership and support are needed to ensure that scale-up of human milk banking includes appropriate quality assurance systems.

References

1. Lawrence RA, Lawrence RM. *Breastfeeding: A Guide for the Medical Profession*, 6th ed. Philadelphia: Elsevier Mosby; 2005.
2. Chantry CJ, Wiedeman J, Buehring G, Peerson JM, Hayfron K, K'aluoch O, et al. Effect of flash-heat treatment on antimicrobial activity of breastmilk. *Breastfeed Medicine*. 2010 Nov 23 [E-pub ahead of print].
3. Chantry CJ, Israel-Ballard K, Moldoveanu Z, Peerson J, Coutsooudis A, Sibeko L, Abrams B. Effect of flash-heat treatment on immunoglobulins in breastmilk. *Journal of Acquired Immune Deficiency Syndrome*. 2009;51(3):264–267.
4. Israel-Ballard K, Abrams B, Coutsooudis A, Sibeko L, Chantry C. Vitamin content of breastmilk from HIV-1 infected mothers before and after flash-heat treatment. *Journal of Acquired Immune Deficiency Syndrome*. 2008;48(4):444–449.

TO LEARN MORE

Please contact:

PATH's South Africa Country Program
PO Box 1985
Parklands 2121
Johannesburg
Phone: (27-11) 447-1641

or The Human Milk Banking Association of South Africa (www.hmbasa.org.za)
email: info@hmbasa.org.za



PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being.

MAILING ADDRESS
PO Box 900922
Seattle, WA 98109 USA

info@path.org
www.path.org

STREET ADDRESS
2201 Westlake Avenue
Suite 200
Seattle, WA 98121 USA

July 2011