

Annual Human Milk Bank Operations Disclosure 2025

Each year, Mid-Atlantic Mothers' Milk Bank (MAMMB) provides the facilities that it serves with important information regarding its operational procedures.

Accreditation and Licensure

- MAMMB strictly follows the guidelines of and is accredited by the Human Milk Banking Association of North America (HMBANA). HMBANA provides evidence-based guidelines for the safe and ethical screening of donors, processing of milk, testing of milk, and distribution. MAMMB is regularly inspected by HMBANA to confirm adherence to the guidelines. The last routine HMBANA onsite inspection occurred in January 2024 and the last HMBANA audit occurred April of 2025.
- MAMMB is licensed as a milk bank in the Commonwealth of Pennsylvania.
- MAMMB is licensed as a tissue bank in the states of Maryland and New York.
- MAMMB considers its general service area to be PA, WV, MD, NJ and DE. At this time, only PA, NY, and MD regulate milk banks.
- The federal government currently categorizes donor milk as food production. MAMMB is registered with the FDA as a food production facility and is subject to inspection. The last routine FDA inspection occurred in January 2024.
- 2 MAMMB staff members are certified Preventive Controls Qualified Individuals (PCQIs). The Preventive Controls for Human Food regulation (often referred to as FSMA) is a law enacted to ensure the safe preparation of food products for human consumption in the US in order to prevent food borne illnesses. Certification involves a week of training in the development and application of risk-based preventive controls.

HMBANA Requirements

- *Donors:* Donors are volunteers and are not compensated in any way. Donors are carefully screened in a process that includes: 1) an interview by phone or in person; 2) completion of a medical history questionnaire; 3) statements of health from the health care providers of the donor and her infant; and 4) blood screening which includes HIV, Hepatitis B and C, HTLV, and syphilis. HMBANA prohibits donor remuneration due to ethical and safety concerns.
- *Pasteurization:* The Holder Method of Pasteurization, a low temperature (62.5°C for 30 minutes) process, is used to inactivate pathogens while maintaining important bioactive components such as Secretory IgA and Human Milk Oligosaccharides (HMOs). MAMMB uses *Thermo Scientific* shaking water baths, and custom built pasteurizers.
- *Temperature Monitoring:* Freezers are maintained no higher than -20°C and refrigerators no higher than 4°C. All temperatures are monitored through *Digi SmartTemps*.
- *Post Pasteurization Bacterial Cultures:* Cultures are performed by the AHN Jefferson Hospital Microbiology Laboratory. Per HMBANA guidelines, milk batches that show any growth post-pasteurization are not distributed.
- *Maintenance of Records:* All information pertaining to distribution, milk testing, and donor screening are retained for every batch for a minimum of 10 years. This information can be provided within 6 hours of the receipt of the batch numbers in question and includes: de-identified screening information from every donor of the batch (including blood

screening), post pasteurization bacterial cultures, drug testing results of the milk pool, and nutrient analysis of the batch. MAMMB performs a mock recall annually.

- *Medical Director:* MAMMB's volunteer Medical Director is Jennifer Zarit, MD, IBCLC, FAAP, NABBLM-C.
- *Medical Advisory Board:* The Medical Advisory Board includes members with expertise in a variety of areas including neonatology, pediatrics, obstetrics, pharmacology, and infectious diseases.

Additional Testing Done by MAMMB but Not Required by HMBANA or State Regulation

- *Drug Testing:* Each pool of milk is tested for a panel of common drugs including amphetamines, benzodiazepines, cocaine, cotinine, and THC using a microplate reader and ELISA kits from Neogen.
- *Macronutrient Analysis:* Each batch of donor milk is tested for protein, fat, and carbohydrate content using the Miris Human Milk Analyzer, the first and only FDA approved device for the measurement of human milk nutritional content.

Shipping

- Frozen pasteurized donor milk is shipped to hospitals, birth centers, and outpatients outside of the greater Pittsburgh area via FedEx or UPS priority overnight shipping.
- For added tracking, MAMMB uses PeriShip or Unishippers, perishable items logistics companies for FedEx or UPS, respectively.
- Dry ice is used to ensure that bottles arrive frozen.
- Frozen pasteurized donor milk is transported to facilities in the greater Pittsburgh area by the hospital's courier.

Distribution Policy

- MAMMB has a Distribution Policy in place that prioritizes NICUs and outpatients with medical needs in the unlikely event of a shortage. This distribution policy adheres to the recommendations of HMBANA.
- Per HMBANA guidelines, NICUs are provided with donor milk that has a minimum of 19.5 Kcal/oz and 0.7 g protein/dL. Donor milk that does not meet this minimum is distributed to outpatients only.

Depots and Dispensaries

- Through community partner hosts, MAMMB has a growing number of Depots and Dispensaries to provide greater convenience for donor families, increased access for recipient families, and to establish local visibility in the communities within its service area.
- Donor Depots house a secure freezer to collect milk from approved MAMMB donors.
- Dispensaries store and distribute small quantities of bottled, pasteurized, frozen donor milk to recipient families.
- Depots and Dispensaries are hosted by health systems, lactation centers, birth centers, physician's offices, and other maternal and child health related facilities. A site may be both a Depot and a Dispensary.
- For more information and a list of Depots and Dispensaries, visit the "Donor Milk in Your Neighborhood" section of midatlanticmilkbank.org.

Hospital Guidebook

This document is only a brief overview of key elements of MAMMB's operations. For more detailed information, please refer to MAMMB's "Pasteurized Donor Human Milk: A Guidebook for Hospitals and Birth Centers Served by Mid-Atlantic Mothers' Milk Bank" and midatlanticmilkbank.org.

Facility Portal

A copy of this letter, the hospital guidebook, and the most current certificates of the items listed below are available on the Facility Portal at midatlanticmilkbank.org. Scroll to the bottom of the home page and click "Portal Login" or use the QR code below. The Portal password is theperfectfood

Current HMBANA Accreditation

Current Pennsylvania License

Current Maryland License

Current New York License

FDA Facility Registration

PCQI Certificates

CLIA certificate of accreditation for AHN Jefferson Regional Medical Center



Updated April 15, 2025 by Denise O'Connor, Executive Director