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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

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06/21/2024

Date

ARKANSAS DEPARTMENT OF HEALTH

STANDARDS PERTAINING TO HUMAN BREAST MILK BANK



PROMULGATED UNDER THE AUTHORITY OF

ARK. CODE ANN. §20-7-140

Effective Date: July 1, 2024

**Arkansas Department of Health
Renee Mallory, RN, BSN
Secretary of Health**

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Director and State Health Officer**

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Section 1. Authority and Purpose

- 1.1 Pursuant to Act 216 of 2019, the Department of Health establishes the following standards for transporting, processing, and distributing commercial human breast milk on a for-profit or nonprofit basis. See Ark. Code Ann. § 20-7-140.

Section 2. Definitions

- 2.1 **Clean**—Physically remove dirt and debris by using detergents and water. An example of an appropriate detergent is common kitchen dish detergent.
- 2.2 **Collection**—The act of obtaining donor human breast milk.
- 2.3 **Disinfect**—Destroy or inactivate most microorganisms on hard surfaces. Disinfection requires specific times of exposure to agents; follow manufacturer’s instructions.
- 2.4 **Distribution**—The delivery of pasteurized donor human breast milk (PDHBM) from a human breast milk bank to a hospital or other entities appropriate to receive breast milk (e.g., researchers, family with a prescription).
- 2.5 **Donor Human Breast Milk Bank**—A donor human breast milk bank is a service established for the purpose of recruiting and collecting breast milk from donors, and processing, screening, storing, and distributing donated breast milk, in accordance with these rules, to meet the specific needs of individuals.
- 2.6 **Donor Human Breast Milk**—Donor human breast milk is milk expressed and donated by lactating women, subjected to a validated pathogen inactivation method, and dispensed for use by a recipient who is not the donor’s own baby. Human Breast Milk banks may use the following additional terms; if terms are used, they comply with the following definitions:
 - 2.6.1 **Fresh-raw breast milk** – Human breast milk expressed within 72 hours and stored at or below 4°C.
 - 2.6.2 **Fresh-frozen breast milk** – Fresh raw human breast milk that has been frozen at -18°C for not longer than 12 months from date of collection.
 - 2.6.3 **Holder pasteurized breast milk** – Fresh-raw and/or fresh-frozen breast milk that has been subjected to a validated method of pathogen reduction.
 - 2.6.4 **Pooled breast milk** – Human breast milk combined with deposits from more than one donor.
 - 2.6.5 **Preterm breast milk** – Human breast milk expressed within the first 4 weeks postpartum by a mother who delivered at or before 36 weeks gestation.
 - 2.6.6 **Term breast milk** – Human breast milk pumped by mothers giving birth after 36 weeks, or before 36 weeks but after 4 weeks postpartum.

- 2.6.7 **Reduced fat breast milk** – Breast Milk that is separated and de-fatted for chylothorax patients or other patients requiring low fat milk (<1g/dl fat content).
- 2.6.8 **Early term breast milk** – Breast Milk that is collected from term mothers (>37 weeks gestation) during the first month of lactation.
- 2.6.9 **Dairy restricted** – Breast Milk expressed by mothers who report avoidance of explicit and implicit dairy products (including all processed foods).
- 2.6.10 **Pasteurized donor human breast milk (PDHBM)** – Donor human breast milk that has been collected, processed, and dispensed according to these rules.
- 2.7 **Donor Human Breast Milk-Contact Surfaces**—All surfaces that contact donor human breast milk during the normal course of operations. This includes utensils and food-contact surfaces of equipment, such as flasks, bottles, and caps.
- 2.8 **Donor Human Breast Milk Depot**—A donor human breast milk depot is an agency affiliated with a donor human breast milk bank that collects and stores donor breast milk that is then transported to the affiliated breast milk bank for processing. The breast milk bank accepts responsibility for all screening, processing, and distributing of milk.
- 2.9 **Donor Human Breast Milk Distribution Site**—A donor human breast milk distribution site is an agency affiliated with a breast milk bank that stores and distributes donor breast milk that was processed by a breast milk bank, and distributes the breast milk to hospitals or outpatients according to these rules.
- 2.10 **Equipment, Clean**—Equipment that is cleaned and maintained according to manufacturer’s instructions and to applicable local and federal regulations for commercial food preparation.
- 2.11 **Breast Milk Donor**—A lactating woman who voluntarily contributes milk to a human breast milk bank.
- 2.12 **Breast Milk-Processing Centers**—For-profit entities that collect human breast milk and produce human breast milk-based products.
- 2.13 **Breast Milk Sharing**—The practice of one mother giving her breast milk to another person without payment.
- 2.14 **Processing**—The use of evidence-based methodologies, including pasteurization, to prepare safe breast milk for recipients.
- 2.15 **Processing Fees**—Fees assessed by the donor breast milk bank to offset the cost of donor screening, breast milk processing, storing, distribution, and record keeping.
- 2.16 **Product Recall**—The formal process of recalling all dispensed breast milk within a batch or batches that are suspected may potentially cause harm.

- 2.17 **Product Replacement**—The process of dispensing additional breast milk to a recipient or recipients after the initial dispensed breast milk has been identified as unacceptable, but not unsafe.
- 2.18 **Quality Control Operation**—A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the Code of Federal Regulations, Title 21, reserved for rules of the U.S. Food and Drug Administration.
- 2.19 **Sanitize**—Reduce microbial load to increase safety and decrease risk of contamination without adversely affecting the product or its safety for the consumer. An example of a sanitizing agent is 70% or higher isopropyl alcohol.
- 2.20 **Sterilize**—Destroy all microorganisms, including spores, via autoclave or other method(s) of sterilization.

Section 3. Administrative Structure

- 3.1 The breast milk bank operations are overseen by qualified nursing, medical, or other breast milk bank personnel with education and training critical to the provision of safe donor human breast milk.
- 3.2 Donor breast milk banks should have a panel of consultants that include specialist in neonatology/pediatrics, lactation, and microbiology/infectious diseases; and may include representation from, but not limited to, the following specialties: nursing, immunology, pharmacology, nutrition, public health, obstetrics, pathology, food technology, law, and consumer representation. These consultants agree to be accessible to the breast milk bank director when appropriate.
- 3.3 All breast milk banks are expected to operate under rules of the Health Insurance Portability and Accountability Act (HIPAA).

Section 4. Donor Qualifications/Screening

- 4.1 Donor qualifications are based on best practices and clinical data, and must be updated continuously to reflect emerging diseases and new pharmaceutical agents.
- 4.2 Screening must include in-person or on-the-phone contact, and must never be limited to electronic communication.
- 4.3 Two appropriately trained staff members must review, approve, and sign or document the completed donor screening.
- 4.4 Acceptable donors are healthy lactating women with surplus expressed breast milk, and who meet the following requirements:
 - 4.4.1 They have been screened verbally and in writing, and given educational materials informing them of characteristics of the high-risk groups or activities that might put them at risk for transmitting blood-borne diseases.

- 4.4.1.1 In cases where English is not a primary language for the donor applicant, and indications are that a translator is required, the contacted breast milk bank makes efforts to offer an appropriate translator to help with the screening process, or a breast milk bank employee who is trained in screening will be present (or available by phone) during the interview with a third-party translator. The translator may also be someone who knows the would be donor and has the donor's permission to translate. This choice is made with discretion, as the breast milk bank screener must feel comfortable that the translator is not manipulative of the would-be donor and is sufficiently mature to handle content.
 - 4.4.1.1.1 If a suitable translator is not available, the donor applicant can be referred to another donor breast milk bank. If no bank is able to find a suitable translator, the donor applicant is deferred due to inadequate screening.
- 4.4.2 Potential donors have statements of known health/medical risks signed by their licensed health care providers.
- 4.4.3 Potential donors are screened serologically for HIV-1 and -2, HTLV-1 and -2, Hepatitis C, Hepatitis B, and syphilis within 6 months prior to the first donation. A CLIA certified high complexity clinical laboratory or an ISO 15189 accredited clinical laboratory, that achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body, does the tests, and results are valid throughout the time of donation unless life-style or medical issues suggest an increased risk for donation, in which case deferral or retesting is at the discretion of the individual breast milk bank.
 - 4.4.3.1 Communication with a breast milk donor regarding her health and lifestyle is expected to be no less frequent than every 2 months and documented in the donor's record. Donors thought to be at risk for a blood-borne disease are immediately deferred.
- 4.4.4 Certain medications are permitted during donation of milk, and others are a cause for deferral. Permissible medications should be reviewed by the Medical Director and approved by the breast milk bank's panel of consultants at least annually and updated based on research and information from the U.S. Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, Health Canada, pharmaceutical and blood-banking industry and other sources. Members of the panel draw from specialties including neonatology, pharmacology, and pediatrics.
 - 4.4.4.1 The determination of any medication's risk takes into consideration characteristics such as molecular weight of a

medication, lipid solubility and plasma affinity, and weight of the likely recipient.

- 4.4.4.2 Prospective donors taking medications on the permissible list but with a deferral time can be accepted. However, breast milk expressed during the deferral period cannot be used to feed babies.
- 4.4.4.3 If a potential donor is donating previously expressed breast milk, medication and herb use during the time of breast milk expression must be investigated.
- 4.4.4.4 Donors should be advised that if they begin taking any medication once approved and donating breast milk, they should contact the breast milk bank to discuss deferral dates or the need to retire as a donor. Moreover, if a prospective or approved donor is taking a medication used for a diagnosis that is outside of the category for the medication, please ask for the dose and forward the information to the medical director, so that a determination can be made about safety.
- 4.4.4.5 Prospective donors taking medications as determined in Section 4.4.4 do not need deferral.
- 4.4.4.6 The use of other medications on a temporary basis may be acceptable if the appropriate deferral period is followed. For most medications, this deferral is 5 times the half-life of the medications.

Section 5. Drugs or Classes That Require Longer Waiting Periods

- 5.1 Certain Drugs or Classes require longer waiting periods:
 - 5.1.1 Radiopharmaceuticals (e.g., radio-iodine) – 2 months
 - 5.1.2 Live-virus vaccines – 2 months
 - 5.1.2.1 Measles mumps rubella varicella (MMRV – this vaccine is not used in the US)
 - 5.1.2.2 Polio (oral)
 - 5.1.2.3 Rotavirus
 - 5.1.2.4 Varicella (“chicken pox vaccine”) (VAR or MMRV)
 - 5.1.2.5 Yellow fever
 - 5.1.2.6 Live typhoid vaccine (there is an inactivated vaccine that requires no deferral period)

Section 6. Disqualification Criteria (Temporary Deferral and/or Total Exclusion)

- 6.1 Note: Potential donors may be temporarily deferred or totally excluded based on the following clinical issues unique to human breast milk and infants, and on current AABB, US CDC, or other regulatory guidelines.
- 6.2 Recent history of blood transfusion
- 6.3 Organ or tissue transplant
- 6.4 Body piercing, tattoos, or permanent makeup
- 6.5 Positive serological test results for HIV, HTLV, Hepatitis B or C.
- 6.6 Risk of Creutzfeldt-Jakob Disease (CJD)
 - 6.6.1 Travel deferrals related to CJD risk
- 6.7 Risk of food borne illnesses.
- 6.8 Vegans not supplementing with B12.
- 6.9 Alcohol consumption.
Smoking or use of tobacco /nicotine products
- 6.10 Medication use (non-approved medications)
- 6.11 Use of illegal recreational drugs.
- 6.12 At risk sexual partner.
- 6.13 Breast Milk that has been heat-treated in any way by the donor.

Section 7. Serological Tests

- 7.1 A certified laboratory is to conduct screening blood tests (HIV-1 and -2, HTLV-1 and -2, hepatitis C, hepatitis B, and syphilis) within 6 months prior to a woman's becoming a donor.
- 7.2 The prenatal care or postpartum care providers may submit testing if it was done within this time frame. Negative test results do not require confirmatory testing.
- 7.3 Screening tests for the following disease are required:
 - 7.3.1 HIV-1, HIV-2
 - 7.3.2 HTLV-1, HTLV-2
 - 7.3.3 Hepatitis B
 - 7.3.4 Hepatitis C
 - 7.3.5 Syphilis
- 7.4 Screening tests apply to all individuals who apply to be donors. If a screening test is positive, the breast milk bank can defer that donor or follow up with a confirmatory

diagnostic test. A confirmatory diagnostic test cannot be a repeat of the same test but must be more specific and less subject to a false positive, according to medical standards. Screening tests include:

- 7.4.1 HIV antibodies for both types (HIV, group O is included in HIV-1)
 - 7.4.2 HTLV antibodies for both types
 - 7.4.3 Hepatitis B surface antigen
 - 7.4.4 Hepatitis C antibody
 - 7.4.5 Syphilis RPR (this test has the highest likelihood of indicating a false positive)
- 7.5 Confirmatory tests may be ordered after obtaining a positive or indeterminate screening test, rather than deferring the potential donor. Confirmatory tests include:
- 7.5.1 HIV PCR (measurement of viral particles)
 - 7.5.2 HTLV PCR
 - 7.5.3 Hepatitis B PCR
 - 7.5.4 Hepatitis C PCR
 - 7.5.5 FTA (florescent treponemal antibody – confirmatory test for syphilis)
- 7.6 Breast Milk banks are not required to run diagnostic tests; however, they may do so. Diagnostic test results override screening test results.
- 7.7 Donors are deferred indefinitely for any positive result on a diagnostic/confirmatory serological test. A donor deferred for positive blood testing is to be referred to a health care provider of her choice. The follow-up is done in compliance with the state/federal regulations. Any breast milk from this potential donor, that has already been donated and is being held at the breast milk bank, is disposed of according to institutional protocols. In the absence of institutional protocols, expressed breast milk may be disposed of in a sink or a trash can.
- 7.8 In all cases, whether or not screening tests are negative, a donor is deferred if her lifestyle or medical risks suggest that she could have harmful substances in her breast milk.

Section 8. Donor Approval

- 8.1 Each breast milk bank defines who is designated to approve or defer donors, based on their credentials, education, and training; and to verify that the screening process is complete, and breast milk is appropriate for processing and dispensing. Donors are notified once they are approved; and communication regarding changes in health, medical, and lifestyle status of the donor and/or anyone in the household are actively encouraged on a regular basis. Breast milk banks must engage in, and document, ongoing communication with donors at a minimum of every 2 months.

- 8.2 Breast milk banks can determine individual circumstances under which they received breast milk before a donor is approved; however, returning raw donated breast milk to the approved or unapproved breast milk donor is not recommended. The final decision on a request for breast milk return is up to each breast milk bank and their medical and legal advisors.

Section 9. Public Health or Medical Crisis

- 9.1 In the case of a medical or public health crisis, each breast milk bank is responsible for having a disaster plan covering emergencies affecting their individual breast milk bank. These plans should include how to protect breast milk in the case of power outage, and notification plans for staff, community, and other breast milk banks or effected entities in case of inability to dispense or receive breast milk.

Section 10. Donor Education and Procedures

- 10.1 To ensure the highest level of safety and quality of donated breast milk, breast milk donors are instructed on the appropriate methods for clean expression, handling, storage, and transportation of human breast milk.
- 10.2 Donors are given written instructions covering:
- 10.2.1 Clean technique for breast milk collection, including:
 - 10.2.1.1 Washing pump parts
 - 10.2.1.2 Handwashing
 - 10.2.1.3 Appropriate containers for storing donor breast milk
 - 10.2.1.4 Handling of breast milk containers
 - 10.2.2 Those times when the donor should refrain from donating, and lifestyle choices that may affect her eligibility as donor.
 - 10.2.3 Labeling of donated breast milk, which includes donor identification and date of collection.
 - 10.2.4 Optimal freezing and storage of breast milk.
 - 10.2.5 Transporting breast milk safely to the bank.
 - 10.2.5.1 In situations where the breast milk was collected before the donor contacted the breast milk bank, the screening process includes discussion and evaluation of how the donor expressed and stored the breast milk, as well as what medications or supplements the donor took during the collection period.

Section 11. Procedure Manual

- 11.1 A breast milk bank maintains a detailed procedures manual, available to breast milk bank personnel at all times. The procedures manual is reviewed annually and signed

by the medical doctor, hospital department head, or other qualified individual overseeing the milk bank.

Section 12. Building and Facility

- 12.1 Breast milk processing buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for breast milk-processing purposes. The building and facilities:
 - 12.1.1 Provide sufficient space for placement of equipment and storage materials to permit sanitary operations and production of donor human breast milk.
 - 12.1.2 Permit the use of proper precautions to reduce the potential for contamination of breast milk, breast milk-contact surfaces, or breast milk-packaging materials.
 - 12.1.3 Are constructed in such a manner that floors, walls, and ceilings may be adequately kept clean and in good repair. Any droplets or condensates from fixtures, ducts, and pipes do not contaminate breast milk, breast milk-contact surfaces, or breast milk-packaging materials. Aisles or working spaces are provided between equipment and walls, and are adequately unobstructed and of adequate width to permit employees to perform duties and to protect against contaminating breast milk or breast milk-contact surfaces, and breast milk-packaging materials.
 - 12.1.4 Allow no pests in any area of the breast milk bank. Effective measures are taken to exclude pests from the processing areas and to protect against the contamination of breast milk on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of breast milk, breast milk-contact surfaces, and breast milk-packaging materials.
 - 12.1.5 Do not allow persons unnecessary to breast milk processing into the breast milk preparation area while open containers of breast milk are being processed.
 - 12.1.6 Properly identify cleaners and sanitizers, which are stored in dedicated containers and kept away from the breast milk in processing.
 - 12.1.7 Provide adequate hand-washing facilities, including a lavatory fixture (sink) with either hot/cold or warm running water, soap, or detergent and individual sanitary towels.
 - 12.1.8 Provide that pasteurizing, pouring, cooling, and labeling of breast milk occur in one room with a separate door, which is closed whenever breast milk containers are open.
 - 12.1.9 Provide a separate room for the cleaning of equipment and containers. In the absence of separate rooms, the cleaning of equipment is done after breast milk processing is complete.

- 12.1.10 Provide designated areas or rooms for the receiving, handling, and storage of returned (recalled) breast milk and breast milk products. Freezer space for the returned product must not be comingled with raw frozen or pasteurized breast milk, although both raw and processed breast milk can be in different sections of the same freezer.
- 12.1.11 Provide separate freezers to store incoming raw-frozen donor breast milk and pasteurized breast milk. Minimally, breast milk can be stored in the same freezer but must be clearly separated, labelled, and identifiable in the same freezer.
- 12.1.12 Provide toilet facilities that do not open directly into any room in which breast milk and/or breast milk products are processed. Restrooms must be completely enclosed, with the door kept closed, and include signage for handwashing. Lab staff must scrub back into lab after use of the restroom.
- 12.1.13 Provide a water supply in compliance with city, state, or township ordinances for potable water.

Section 13. Equipment

- 13.1 Recording thermometers monitor freezer temperatures, or freezers are equipped with temperature-sensitive alarms. Two distinct and appropriately calibrated thermometers – whether electronic, indwelling, or mercury -- monitor freezers. Breast milk bank personnel investigate and resolve discrepancies in thermometer readings.
- 13.2 Freezers are locked or in a secured area.
- 13.3 Breast milk is stored in dedicated freezers that maintain breast milk in a frozen state. Freezer temperature is held no higher than -18°C (or 0°F) and any lower temperature is acceptable. Brief fluctuations in temperature secondary to opening the doors or self-defrosting cycles are acceptable as long as breast milk remains frozen.
- 13.4 Refrigerators used for storing thawed or processed breast milk are held no higher than 4°C (or 40°F).
- 13.5 Storage and processing equipment are calibrated every six (6) months, or according to manufacturers' instructions.
- 13.6 All equipment manuals are available to breast milk bank personnel at all times.
- 13.7 Equipment intended for human breast milk banking – processing or storing – is used only for breast milk banking purposes.
- 13.8 Processed breast milk is stored in glass or food-grade plastic that meets FDA requirements for both freezing and heating temperatures used in processing. Documentation of such is maintained in the breast milk bank.

- 13.9 All equipment used in the breast milk bank is cleaned and maintained according manufacturer's instructions, including, but not limited to, freezers, refrigerators, pasteurizers, shaking water baths, dishwashers, thermometers, alarms, and breast milk composition analysis equipment.
- 13.10 All breast milk bank equipment and utensils are designed and made from material that can be adequately cleaned and maintained. The design, construction, and use of equipment and utensils do not result in the adulteration of breast milk with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be installed and maintained to facilitate the cleaning of the equipment and of all adjacent spaces. Breast milk-contact surfaces are corrosion-resistant when in contact with breast milk. They are made of nontoxic materials and designed to withstand the environment of their intended use and the action of breast milk, and, if applicable, cleaning compounds and sanitizing agents. Breast milk-contact surfaces are maintained to protect breast milk from being contaminated by any source, including unlawful indirect breast milk additives.
- 13.11 Seams on breast milk-contact surfaces are smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.
- 13.12 Equipment that is in the manufacturing or milk-handling area and that does not come into contact with breast milk is constructed so that it can be kept in a clean condition.
- 13.13 Holding, conveying, and manufacturing systems – including gravimetric, pneumatic, closed, and automated systems – are of a design and construction that enables them to be maintained in an appropriate sanitary condition.

Section 14. Thermometers

- 14.1 Monitoring temperatures in milk banks is critical to the safety of the breast milk distributed.
- 14.2 The quality and accuracy of thermometers used to monitor temperatures in refrigerators and freezers and at critical points in the pasteurization process must be verified.
- 14.3 Thermometers in freezers and refrigerators
 - 14.3.1 A minimum of two (2) calibrated thermometers are used to monitor temps in freezers and refrigerators.
 - 14.3.2 Thermometers may be certified calibrated by a national metrology institute (NMI) such as the National Institute of Standards and Technology (NIST) or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of reference thermometers. The milk bank shall verify working thermometers

against the calibrated reference thermometers at least quarterly. The breast milk bank must keep records of calibration and verification records.

Section 15. Thermometers used in the Pasteurization Process

- 15.1 When using equipment specially designed for human breast milk pasteurization, the procedures for the use of the machine are followed and the machine is calibrated and maintained per manufacturer's guidelines. Documentation that equipment is maintained per manufacturer's guidelines is required.
- 15.2 When pasteurizing using manual equipment (reciprocal shaking water baths): Thermometers used in control bottles to record the temperature of breast milk during heating and cooling phases should be NIST-certified or calibrated no less often than quarterly using an NIST-certified reference thermometer. The breast milk bank must keep records of calibration.
 - 15.2.1 In addition to the quarterly calibration, thermometers should be calibrated if dropped, damage, or at any time the accuracy is in question.
 - 15.2.2 Thermometers used to monitor the heat processing and cooling of donor breast milk using manual equipment should have as small a standard deviation range as is practical. Thermometers with a standard deviation of +/- 0.2° Celsius or less are recommended.

Section 16. Thermometer Calibration Procedure

- 16.1 Use the ice-point method: Insert the thermometer probe and the reference thermometer probe into a container of ice and water. Allow the temperature to stabilize. Compare readings and adjust thermometer to reference thermometer reading according to the manufacturer's directions and/or service or replace thermometer.
- 16.2 Hot-point calibration method: Immerse the thermometer probe and the reference thermometer probe into water set at 65°Celsius. Allow the temperature to stabilize. Compare readings and adjust thermometer to reference thermometer reading according to manufacturer's directions and/or service or replace thermometer.

Section 17. Breast Milk Analyzers

- 17.1 Nutritional analysis of breast milk is not a minimum requirement for breast milk banks. However, if a breast milk bank chooses to use a nutritional analyzer, it is used within the following parameters:
 - 17.1.1 The instrument is maintained following manufacturer's directions.
 - 17.1.2 The breast milk bank reports annually to recipient hospitals about what instrument it is using for analysis.

- 17.1.3 The instrument uses data based on credible scientific statistical analysis, with attention to false-positive and false-negative values, variation from the mean and median, and standard deviation.
- 17.1.4 Breast milk banks that use human breast milk analyzers are responsible for the accuracy of results and should ensure they follow the Food and Drug Administration (FDA) Good Laboratory Practices regarding regular calibration and record keeping.
- 17.1.5 The Food and Drug Administration (FDA) states in its 2013 Food Labeling Guide, "FDA has not stated how a company should determine the nutrient content of their product for labeling purposes...Regardless of its source, the company is responsible for the accuracy and the compliance of the information presented on its label."

Section 18. Handling

- 18.1 All persons working in direct contact with breast milk, breast milk-contact surfaces, and breast milk-packaging materials adhere to hygienic practices while on duty to the extent necessary to protect against contamination of breast milk.
- 18.2 The methods for maintaining cleanliness include, but are not limited to:
 - 18.2.1 Wearing outer garments suitable to the operation in a manner that protects against the contamination of breast milk, breast milk-contact surfaces, or breast milk packaging materials. Wear a gown, apron, or lab coat that covers clothing.
 - 18.2.2 Maintaining adequate personal cleanliness.
 - 18.2.3 Washing and sanitizing hands and arms from elbows downward thoroughly before starting work, whenever work area is left and become soiled or contaminated. Immediately dry hands and arms with an individual single-use-only towel. Put on disposable gloves after washing hands.
 - 18.2.4 Not washing hands in sinks used for milk preparation or washing equipment. Keeping hand-washing facilities in a clean condition and in good repair.
 - 18.2.5 Removing all unsecured jewelry or other objects that might fall into breast milk, equipment, or containers. Rings may be left on fingers and covered by gloves after hands are washed.
 - 18.2.6 Covering hair with hair nets, caps, or other effective hair restraints; include beard covers when appropriate. Dangling earrings must be tucked under hair net.
 - 18.2.7 No eating food, chewing gum, drinking beverages, or using tobacco in areas where breast milk may be exposed or where equipment or utensils are washed.

- 18.2.8 Excluding everyone with an illness – e.g., vomiting, diarrhea, jaundice, sore throat with fever, and open lesion, or other abnormal source of microbial contamination – from the breast milk-processing and breast milk-handling areas.
- 18.2.9 Reporting potential exclusion to a breast milk bank staff member designated to decide appropriateness of potential exclusion.
- 18.2.10 Preparing breast milk in a dedicated clean space with facilities for aseptic technique.
- 18.2.11 Cleaning and sanitizing breast milk-contact surfaces and work areas by a process that is effective in destroying microorganisms of public health significance before handling or processing milk and after any interruption in processing that may lead to contamination.
- 18.2.12 Making clean sinks and sanitizing dispensers available in the breast milk-handling area.
- 18.2.13 Ensuring that personnel responsible for identifying sanitation failures or breast milk contamination have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe breast milk.
- 18.2.14 Ensuring that breast milk handlers and supervisors receive appropriate training in proper food-handling techniques and food-production principles and that they are informed of the danger of poor personal hygiene and unsanitary practices.
- 18.2.15 Ensuring that competent supervisory personnel take responsibility for assuring compliance by all lab personnel.
- 18.2.16 Cleaning all food-contact surfaces, including utensils and food-contact surfaces of equipment, as frequently as necessary to protect against contamination of food.

Section 19. Logging of Incoming Breast Milk

- 19.1 All donated breast milk is identified as relating to a specific approved breast milk donor. Donated breast milk is packaged securely with identification visible, and maintained in a frozen state until chosen for processing. Logging of incoming breast milk includes estimating the volume of breast milk, as well as observing for foreign matter or other sources of contamination such as broken storage containers. Breast milk is discarded if contamination is suspected or if foreign matter is present and unable to be extracted without contamination.

Section 20. Defrosting and Pooling

- 20.1 Breast milk is generally thawed in refrigerators in a manner that prevents the breast milk from becoming adulterated or contaminated. Final thawing may occur outside

of the refrigerator as long as temperature expectations are met. Breast milk should be maintained at 45°F or 7.2°C or below, both while in the refrigerator and out. Breast milk taken from refrigerators for pouring is kept out of direct sunlight and at least 6 feet from any heat source, and refrigerated after pouring. If a water bath is used for thawing, the lids of all containers are kept above the water line. Breast milk should be maintained at 45°F or 7.2°C or below, both while in the refrigerator and out.

20.1.1 Pooling of fresh raw or defrosted fresh-frozen breast milk is conducted under clean conditions.

Section 21. Requirements of Raw Frozen Breast Milk Distribution

- 21.1 Each pool of breast milk has a sample taken for bacteriologic screening using sterile technique.
- 21.2 Only breast milk from pools with $\leq 10^4$ CFU/ml of normal skin flora (e.g., coagulase negative staphylococcus, diphtheroids, Staphylococcus epidermis, or Streptococcus viridians) is acceptable to dispense raw. The presence of any pathogens is unacceptable.

Section 22. Aliquoting and Heat Processing

- 22.1 Aliquoting when using the Holder Pasteurization Method
 - 22.1.1 Pooled breast milk is aliquoted into clean containers. Original containers may be used as long as they have been maintained under clean conditions, manufacturers' documentation confirms that they have multiple-use approval, and they have been appropriately sanitized.
 - 22.1.2 Containers are filled leaving adequate air space in the container to allow for expansion during freezing.
 - 22.1.3 All containers are filled to the same approximate level. Breast milk is examined during pouring for foreign matter. Breast milk is strained and visually examined before heat processing. Any foreign matter should be removed, and, if not removable, the breast milk is discarded.
 - 22.1.4 All containers are tightly closed with clean caps to prevent contamination of breast milk during heat treatment.
 - 22.1.5 Multiple batches may be created from one pool. A "batch" is the set of bottles that fit into a single pasteurizer or shaking water bath at one time.
- 22.2 Heat Processing
 - 22.2.1 When using equipment specifically designed for human breast milk pasteurization, the procedures for use of the machine are followed.
 - 22.2.2 The following guidelines refer to shaking water baths only:

- 22.2.2.1 Aliquots of breast milk are processed by completely submerging the containers in a well-agitated or shaking water bath preheated to a minimum of 62.5°C.
- 22.2.2.2 A control bottle containing the same amount of breast milk or water as the most filled container of breast milk in the batch is fitted with a calibrated thermometer to register breast milk temperature during heat processing. The control bottle follows the same process as the rest of the batch at all times.
- 22.2.2.3 The thermometer is positioned such that approximately 25% of the breast milk volume is below the measuring point of the thermometer, or according to manufacturer's instructions. Probe should not be touching the bottle in any way.
- 22.2.2.4 The monitored aliquot is placed into the water bath with all other aliquots and is either positioned at the coldest area of the water bath, as identified during calibration checks, or positioned according to the manufacturer's instructions.
- 22.2.2.5 After the temperature of the monitored control bottle has reached 62.5°C, the heat treatment continues for 30 minutes, maintaining the temperature, and then ends immediately. Fluctuation during the heating process may be seen for short periods of adjustment, where heat may briefly fluctuate between 62° and 64.5°C.
- 22.2.2.6 Breast milk temperature and bath temperature are monitored and recorded.
- 22.2.2.7 Air bubbles released from breast milk containers indicate insecure caps – such bottles are discarded.

22.3 Chilling and Storage

- 22.3.1 When using equipment specifically designed for human breast milk pasteurization, the procedures for use of the machine are as follows.
- 22.3.2 Following heat processing, the breast milk is rapidly cooled to 4°C (39°F) using either the processing equipment manufactured to cool breast milk, or ice baths. If using ice baths for cooling, water source must be of adequate sanitary quality and the ice-creating equipment must be maintained per manufacturer's instructions. (NOTE: Unless using caps and equipment designed for submersion, caps need to remain above water level to prevent possible contamination from water seepage.)
- 22.3.3 An aliquot of processed breast milk from each batch is cultured for bacteria count.
- 22.3.4 Breast milk is promptly labeled and frozen for storage.

- 22.3.5 Cooled, heat-processed breast milk can be stored, sealed, for up to 72 hours at 4°C for dispensing without freezing once bacteriological culture procedures and standards are met. Breast milk can then be frozen for later use if not needed immediately.
- 22.4 Labeling of Breast Milk
 - 22.4.1 Containers are labeled with batch number and expiration date of not more than 1 year from earliest pumping date of breast milk in pool.
 - 22.4.2 Containers are labeled with the name of the breast milk bank where the processing occurred.
- 22.5 Bar-coding of Breast Milk
 - 22.5.1 Barcode or other automatic tracking systems are not included as a minimum requirement for breast milk banks.
 - 22.5.2 If a breast milk bank chooses to use an automatic tracking system, it is used within the following parameters:
 - 22.5.2.1 The tracking/coding system is maintained following manufacturer's directions.
 - 22.5.2.2 The breast milk bank reports annually to receipt hospitals about what system is being used for tracking.
 - 22.5.2.3 The system would ideally be used by the recipient hospital also, but this is not required.
- 22.6 Bacteriological Testing
 - 22.6.1 Any bacteriological growth is unacceptable for heat-processed breast milk. Individual milk banks have the microbiology Standards of Practice (SOP) available in their banks, distributed by Human Milk Bank Association of North America (HMBANA) or the FDA's Bacteriological Analytical Manual (BAM). Individual breast milk banks ensure that the microbiology lab performing the testing is in compliance with the procedures.
 - 22.6.2 Breast milk that does not meet acceptable bacteriological standards is not distributed to a recipient but may be used for research. If not used for research, the contaminated breast milk is discarded.
 - 22.6.3 The bottle of breast milk for the microbiological sample is chosen randomly from each batch of breast milk and discarded once the sample is taken. It is not resealed and dispensed, and it does not need to be stored for further testing.
- 22.7 Shipping
 - 22.7.1 Breast milk banks follow the standard guidelines of the shipper for ensuring that breast milk arrives at the destination intact and in a frozen

state. Dry ice or blue ice may be used if sufficient in weight or size to keep breast milk frozen.

- 22.7.2 Cold-chain verification may be required in your state or province. A number of technologies exist to verify temperature.

Section 23. Breast Milk Dispensing

- 23.1 All breast milk dispensed is heat-processed unless a prescribing healthcare provider requests fresh frozen or fresh chilled raw breast milk.
- 23.2 In the event that a breast milk bank is unable to supply the needs of its recipients, it should contact other breast milk banks for assistance in supplying breast milk. If unable to locate additional supplies of donor breast milk, it dispenses the breast milk available on a priority basis to the recipients in greatest need. The breast milk bank coordinator/director and/or the medical director makes these decisions, basing them on diagnosis, severity of illness, availability of alternative treatments, and history of previous breast milk use.

Section 24. Transfer of Human Breast Milk

- 24.1 Breast milk may be transferred from breast milk bank to another upon request. The transferring breast milk bank transfers breast milk from approved donors only and establishes a transfer agreement with the receiving bank. The transferring breast milk bank sends its own donor identification number associated with the breast milk deposits, allowing for tracking and recall if a problem occurs, and also allowing for protection of the donors' privacy.
- 24.2 Pasteurized breast milk that is transferred to another bank retains its original label indicating where the processing occurred. The recipient bank may add its own label but should not obscure or remove the original label when dispensing.

Section 25. Breast Milk Bank Records

- 25.1 Donor Records include:
- 25.1.1 Initial donor screening form, documenting:
 - 25.1.1.1 Medical history
 - 25.1.1.2 History of communicable diseases
 - 25.1.1.3 Lifestyle choices that are risks for donated breast milk, including alcohol and nicotine use
 - 25.1.1.4 Use of medications and/or herbs
 - 25.1.2 Confirmation of negative serology tests within 6 months of donation for HIV-1 and -2, HTLV-1 and 2, Hepatitis B, Hepatitis C, and syphilis, and any additional screening required by the individual bank

- 25.1.3 Healthcare provider medical release form for both the donor, acknowledging that the provider(s) knows of no risks to the potential donor should milk be collected for donation.
- 25.1.4 Birth date and gestational age of donor's infant
- 25.1.5 Documentation of each donation (deposit)
- 25.1.6 Signed donor consent form
- 25.2 Administrative records are confidential. Electronic records must be secure (password-protected or encrypted). Paper records must be kept in a secure private area. Breast milk banks inform donors and recipients of privacy policies and procedures.
- 25.3 Donor records are maintained for 10 years if an adult recipient – or until every recipient who has received breast milk from a specific batch reaches a minimum age of 21, or longer, according to individual state or hospital rules or regulations.
- 25.4 Breast milk bank administrative records include:
 - 25.4.1 Identification of donors whose breast milk deposits comprise each pool, and the destination of each pool.
 - 25.4.2 Batch information, including date of heat treatment, volume of breast milk treated, aliquots per batch, and heat-treatment times and temperatures.
 - 25.4.3 Bacteriologic test results by batch after pooling and heat treatment.
 - 25.4.4 Freezer, refrigerator, and pasteurizing temperatures.
 - 25.4.5 Calibration records for all equipment, with calibration cycle and process according to manufacturers' instructions.
 - 25.4.6 Breast milk bank financial records as appropriate per institution, documenting processing fees per volume of breast milk dispensed, financial donations and in-kind gifts, and financial audits, if appropriate.
- 25.5 Recipient records include:
 - 25.5.1 Name of receiving entity and purchase-order number. If ordered by a medical provider with prescription, name of provider and medical necessity.
 - 25.5.2 Dispensing date, batch numbers, number of bottles, and ounces per bottle of all supplied breast milk.
 - 25.5.3 Other pertinent information (such as diagnoses and medical outcome(s) of recipients, when available).
 - 25.5.4 Documentation of quarterly communication with family or prescriber of outpatient recipients.

Section 26. Tracking and Recall of Donor Human Breast Milk

- 26.1 A system of tracking donor breast milk from donor to recipient is maintained.
- 26.2 A mock recall to test the breast milk bank’s ability to track a donation from donor to recipient in 6 hours or less is carried out and documented in a breast milk bank’s first year of operation and every 2 years thereafter. The need to conduct a true recall in any given year negates the need for a mock recall and resets the calendar until a mock recall is needed.
- 26.3 Product replacement is conducted at the discretion of the dispensing breast milk bank.
- 26.4 Individual breast milk banks are responsible for ensuring that they are compliant with their state or federal requirements for operation.
- 26.5 A person designated by each breast milk bank immediately investigates a suspected release of breast milk that does not meet these rules. If a problem is determined, the designated person initiates a root cause analysis and modifies internal procedures as appropriate. It is the individual recalling breast milk bank’s responsibility to gather all data investigating the risk level associated with the suspected error.

Section 27. Research

- 27.1 A breast milk bank may decide whether or not to provide milk for an external research project.
- 27.2 Breast milk banks that use milk for internal and external research purposes state this in their informed Consent of Donors.

Section 28. Annual Assessment and Accreditation

- 28.1 All nonprofit breast milk banks are required to complete an annual Human Milk Banking Association of North America (HMBANA) accreditation. Schedule of assessments for accreditation are set by HMBANA.

CERTIFICATION

I hereby certify that the foregoing Standards Pertaining to Human Breast Milk Bank were duly adopted by the Arkansas State Board of Health on the 26th day of October, 2023.



Jennifer Dillaha, MD
Secretary, Board of Health
Director, Arkansas Department of Health

