

## Improving Outcomes with Human Milk

**Ashlynn Baker, BSN, RN, IBCLC**  
Director, The King's Daughters Milk Bank  
757.668.MILK  
Ashlynn.baker@chkd.org

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## Disclosure

- Director of Milk Bank Services with The King's Daughters Milk Bank at CHKD
- Board Member - Human Milk Banking Association of North America (HMBANA)
- Will discuss the FDA approved, Miris Human Milk Analysis machine; I am not employed nor do I or the Milk Bank in which I am employed receive any funding from this company

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## “Sharing the Health”

- Briefly review the macronutrients and a few human milk immunity factors
- Understand the importance of breastfeeding & human milk
- Discuss HMBANA donor screening and milk processing requirements
- Outline reasons for human milk variability and the benefits of analysis

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## Human milk is...

- Species specific nutrition
- Considered the standard of care
- As valuable as a medication or immunization
- A preventer of acute and chronic disease
- Lifelong protection

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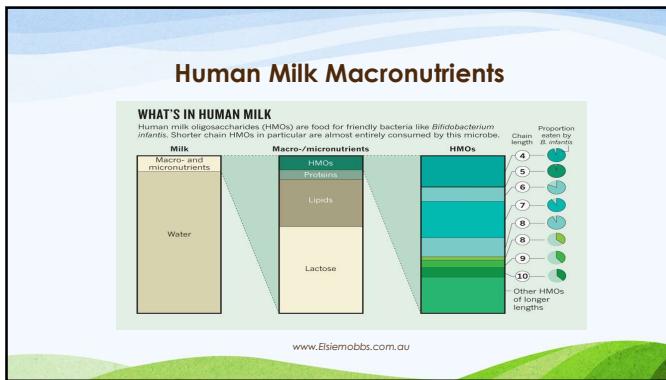
### Species-Specific Nutrition

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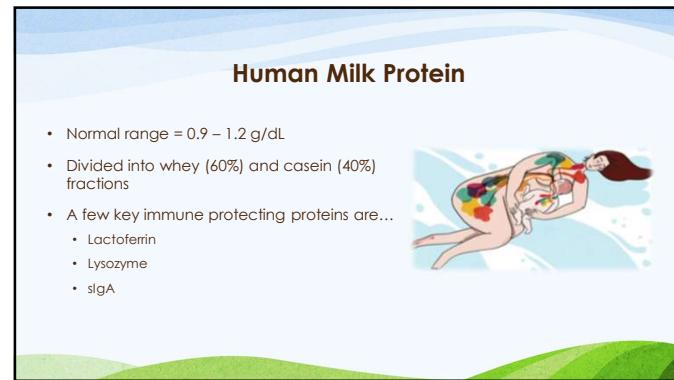
## Benefits of Human Milk Nutrition

- Optimal form of nutrition for nearly all infants
- Easily digested with increased absorption of fat, lactose, minerals and vitamins; more efficient intestinal motility
- High quality, species specific proteins, growth hormones and long chain polyunsaturated fatty acids
- Reduces inflammation
- Lowers gut pH and promotes immunologic maturation of the gastrointestinal tract thereby lowering the risk and extent of microbial dysbiosis

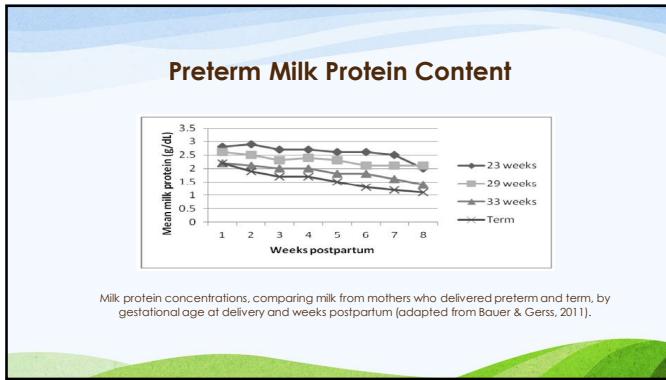
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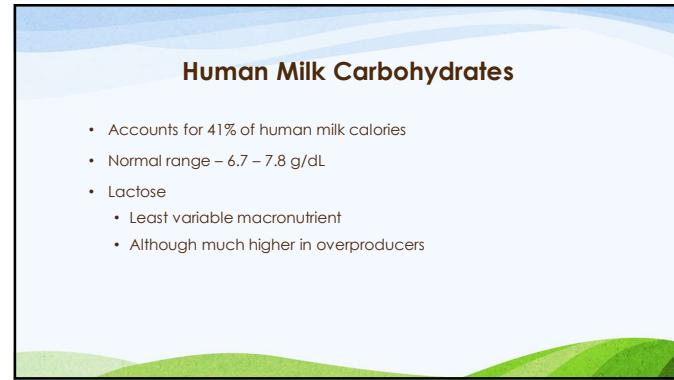
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### Human Milk Carbohydrates

- Oligosaccharides (HMO's)
  - Non-nutritive macronutrient
  - Sugar chains sizing from 3-32 sugars
  - Differ from all other mammals
  - Pathogen binding "decoys"
  - Support the growth of good gut bacteria

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### A Note on Micronutrients...

- Vary depending on maternal diet, gestational age and body stores
  - encourage maternal prenatal vitamins during lactation
  - multivitamins with iron for exclusively donor human milk fed infants
  - vitamin K injections for infant at birth \*
  - supplementation with vitamin D for mother and infant\*
  - iron supplementation for low birth weight or prematurity\*
  - fluoride for infants > 6 months of age if without fluoridated water\*

\*Position of the Academy of Nutrition and Dietetics: Promoting and Supporting Breastfeeding (2015)

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### Additional Human Milk Components...

- maternal immune factors
- macrophages
- stem cells
- cytokines/interleukins
- chemokines
- growth factors
- erythropoietin
- appetite-regulating hormones
- additional microbiome supportive factors

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### Human Milk as a Preventer of Acute and Chronic Diseases?

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### Public Health Statements...

**2012, Position of American Academy of Pediatrics:**  
Given the short- and long-term medical and neurodevelopmental advantages of breastfeeding, infant nutrition should be considered a public health issue and not only a lifestyle choice.

**2015, Position of Academy of Nutrition and Dietetics:**  
Breastfeeding is an important public health strategy for improving infant and child morbidity and mortality, improving maternal morbidity, and helping to control health care costs.  
Research continues to support the positive effects of human milk on infant and maternal health, as it is a living biological fluid with many qualities not replicable by human milk substitutes.

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### Breastfeeding Recommendations...

**2012, Position of American Academy of Pediatrics:**  
The AAP reaffirms its recommendation of exclusive breastfeeding for 6 months, followed by continued breastfeeding as foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant.

**2015, Position of Academy of Nutrition and Dietetics:**  
It is the position of the Academy of Nutrition and Dietetics that exclusive breastfeeding provides optimal nutrition and health protection for the first 6 months of life, and that breastfeeding with complementary foods from 6 months until at least 12 months of age is the ideal feeding pattern for infants.

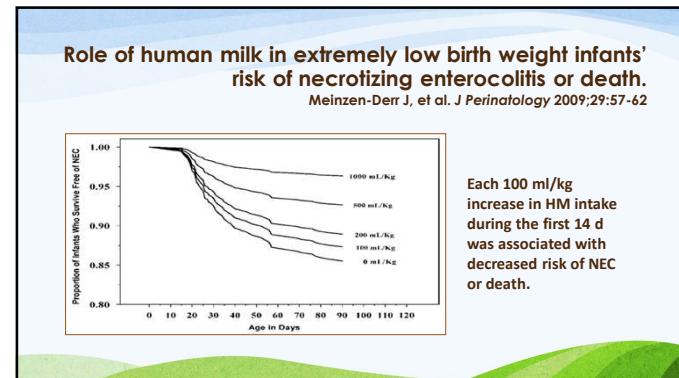
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## IMPACT Statement...

Human milk is considered the optimal form of nutrition for nearly all infants, as the risks of not receiving human milk include increased rates of infant and maternal morbidity, increased health care costs, and significant economic losses to families and employers.

*Position of the Academy of Nutrition and Dietetics: Promoting and Supporting Breastfeeding (2015)*

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## Infant Diseases Reduced by Human Milk Diet

- Acute Otitis Media
- Upper and lower respiratory
- RSV bronchiolitis
- Gastroenteritis
- Asthma
- Allergies
- Atopic dermatitis
- Inflammatory Bowel
- Obesity
- Celiac
- Type 1 and 2 diabetes
- Heart disease
- Leukemia and lymphoma
- SIDS
- NEC, ROP, CLD (Premature)

*Pediatrics* 2012;129:e827-841

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## Maternal Benefits Reduced Risk of:

- Hypertension
- Hyperlipidemia
- Anemia
- Ovarian and breast cancer
- Type II diabetes
- Osteoporosis
- PPD & PPA
- Infant abandonment

*Pediatrics* 2012;129:e827-841

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## Economic Benefits

Spending on preventable disease

Category	Percentage
50% of adults over 21 are affected by chronic conditions such as heart disease, stroke, and diabetes. <sup>4</sup>	50%
Chronic disease, much of which is preventable, accounts for 75 percent of healthcare spending in the U.S.	75%

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## Breastfeeding = Prevention

- Current research suggests that the risk of chronic disease is 20% to more than 200% higher in those who are not breastfed compared to those who were breastfed in infancy. \*
- Breastfeeding in infancy is associated with lower mean serum cholesterol levels in adult life. The effect is significant and larger than dietary advice or multiple risk factor interventions. \*\*
- Studies from Western Europe and North America suggest that breastfeeding has a significant effect on the prevalence of obesity. \*\*
- Breastfeeding has a protective effect on the risk of type 2 diabetes. The effect of breastfeeding is significant and of similar magnitude as diet/dietary advice and exercise.\*\*

\*Source: Smith JP, Harvey PJ. *Public Health Nutrition*, 2010. *Chronic disease and infant nutrition: is it significant to public health?* WHO, 2010 preliminary data  
\*\* Source: Evidence on the long term effects of breastfeeding, WHO, 2007

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### Laying the Path for Future

- First feeding is critical - MOM, PDHM or Formula?
  - Proteins, hormones, antibodies – human vs. bovine
  - Negative impact of artificial feedings on microbiome
    - Gut pH increases and becomes much less protective
    - Artificial feedings lead to delayed intestinal juncture closure

**First feedings have acute and chronic impacts on microbiome!**

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### Critical Take Away...

- Formula, at its best, only replaces most of the nutritional components of breast milk: it is just a food, whereas breast milk is a complex living nutritional fluid containing antibodies, enzymes, long chain fatty acids and hormones, many of which simply cannot be included in formula.
- Furthermore, in the first few months, it is hard for the baby's gut to absorb anything other than breast milk. Even one feeding of formula or other foods can cause injuries to the gut, taking weeks for the baby to recover

[https://www.unicef.org/nutrition/index\\_24824.html](https://www.unicef.org/nutrition/index_24824.html)

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### Pasteurized Donor Human Milk & Milk Banking

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### The Next Best Option...

**2012, Position of the American Academy of Pediatrics:**  
The potent benefits of human milk are such that all preterm infants should receive it. Mother's own milk, fresh or frozen, should be the primary diet. If mother's own milk is unavailable, despite significant lactation support, pasteurized donor milk should be used.

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### Ideal Feeding For a Preterm Infant

1. Breastfeeding at mom's breast
2. Mom's fresh, expressed breast milk
3. Mom's breast milk frozen & thawed
4. Pasteurized donor human milk
5. Premature infant formula
  - Can provide good nutrition
  - Can't provide immunity
  - Provides pro-inflammatory cow proteins, etc.

(infant needs mom's microbiome!)

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**2016, AAP Position Statement:**  
Donor milk banks represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in NICUs and other settings. Families and caregivers may be reassured that, at the time of this publication, there are no reported cases of pasteurized donor human milk causing an infection with hepatitis viruses or HIV and that the likelihood of this type of infection occurring in a neonate given donor human milk is extremely small.

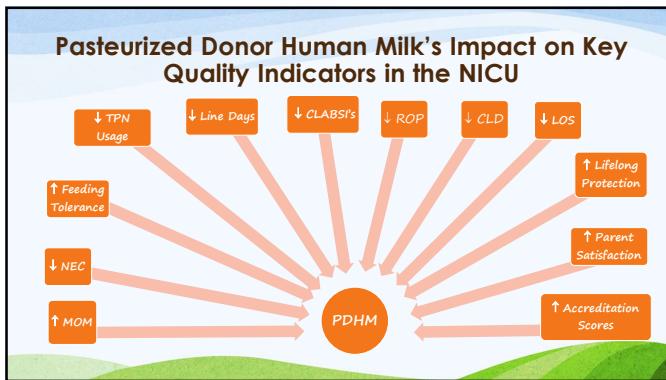
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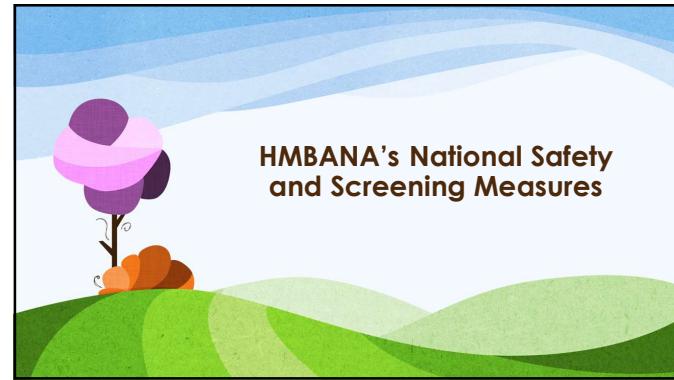
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- ### Novel Uses Gaining Positive Outcomes
- Newborn nursery – first feedings
  - Pre/post op nutrition for complex pediatric heart surgeries
  - Treatment of short gut and other bowel diseases
  - Renal and liver failure
  - Oncology
  - And more...

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Breast Milk is the Best Milk but...

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## What is a Milk Bank?

A human milk bank is a service established to:

- recruit and screen healthy, lactating breast milk donors
- collect donated human milk
- process, screen, store human milk
- distribute culture negative, pasteurized donor human milk to protect, nourish and encourage optimal health

**The mission of a human milk bank is to promote and support breastfeeding by providing safe, high-quality donor milk to fill a gap for those who need mother's milk but cannot receive it.**

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## Human Milk Banking - Donor Selection

Non-profit banks rely on the voluntary, non-remunerated donor:

- An altruistic donor who gives freely and voluntarily without receiving payment in the form of money or a substitute for money
- Evidence shows enhanced donor safety when payment is not rendered
- Per WHO, FDA, CDC, AABB and HMBANA they are the lowest-risk donor vs. other donor types

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## Human Milk Banking - Donor Selection

**Identification**

- Good health: limited meds or free from herbal supplements
- Providing breast milk for own infant
- Bereaved or surrogate mother

**Donor screening methods - 3 steps**

- Verbal-phone interview
- Electronic questionnaire & medical releases from donor & her infant's doctors
- Lab serological testing: HIV, HTLV, Hep B & C, Syphilis

**Education**

- Proper hand & pump hygiene, collection, storage, transportation

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## Taking Care of Our Donors

- Location is never an issue
- No cost to donor
- Arrange and pay for the overnight shipping from home or hospital
- Local donor drive thru
- Specialized care for bereaved, legacy donors
- Reimburse with storage supplies
- Certificates and keepsakes
- Ongoing donor screening and communication until "retire"

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## Human Milk Nutritional Analysis and Milk Bank Processing

- Broad spectrum coverage
- Once homogenized, a sample of the pooled/blended milk is analyzed for fat, crude protein, carbohydrates, total solids, energy and true protein.

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### Labeling and Barcoding

- Milk bottles are labeled with batch number, expiration date, volume, and milk type
- Barcode identifies donors in each batch
- Donor records, pasteurization reports and batch cultures are kept for at least 23 years



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### Pasteurized Donor Human Milk

Pasteurization (62.5C for 30 minutes):

- Removes bacteria and viruses
- Removes some bioactive factors or antibodies
- Preserves human growth factors
- Preserves macronutrients

Final step – culture of milk; must be no growth at 48 hours



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### Dispensation of Pasteurized Donor Human Milk

- Culture negative PDHM is available for shipping throughout North America
- Frozen, perishable treatments are scanned out and shipped via priority overnight shipping on dry ice with cold chain trackers
- Available for hospital use, birthing centers and outpatients

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### Analysis – Part of the Assessment Bundle



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### Macronutrient and Energy Comparison

	Protein	Fat	Lactose	Energy
<b>Human Milk Reference Standard</b>	0.9	3.5	6.7	65-70
<b>Term Donor Milk</b>				
Wojcik et al (2009), n = 415	1.2	3.2	7.8	65
Michaelsen et al (1990), n = 2553	0.9	3.6	7.2	67
<b>Preterm Donor Milk</b>				
Hartmann (2012), n = 47	1.4	4.2	6.7	70

Ballard, O., Morrow, A. (2013) Human Milk Composition: Nutrients and Bioactive Factors, Pediatric Clinicians North America, Feb 60(1): 49-74

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### Not One Size Fits All

The dynamic variability of mother's milk can make meeting fortification goals a challenge. A few of these factors include...

- gestational age at birth
- number of times per day that mother is nursing and/or expressing milk
- stage of lactation
- time of day that milk is expressed
- how long she expresses milk
- maternal diet and BMI
- return of menstruation
- maternal medications

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## Keeping Handling Factors in Mind

There are additional variables that impact the milk composition beyond maternal concerns. A few include...

- the preparation and handling of fresh vs. frozen milk
- lipids adherence to feeding tube sets
- the duration of infant feeding (bolus vs. continuous); continuous feeds link to ↓ fat delivery by as much as 50% vs. bolus at 6%
- the positioning of the feeding syringes during enteral feedings (vertical vs. horizontal)

Continuous Feedings of Fortified Human Milk Lead to Nutrient Losses of Fat, Calcium and Phosphorus.  
Stefanie P. Rogers et al. Nutrients (2010).

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## The Future of Hospital Target Fortification

- With all of these dynamic factors to consider, it is reassuring to know that accurate and feasible nutritional analysis of human milk and the ability to target fortify mother's own milk is becoming available in the United States!
- December 2018 - the FDA approved the first mid-infrared Human Milk Analysis (HMA) system for use in both hospitals and milk banks!

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## FDA's Approval of Human Milk Analysis

- The Miris Human Milk Analyzer infrared spectroscopy system analyzes samples of human milk and provide a quantitative measurement of fat, protein and total carbohydrate content as well as calculations of the total solids and energy content contained in the milk
- Prescription device intended for use by trained health care personnel at clinical laboratories or Milk Banks
- Knowing the macronutrient content of the breast milk may help the health care team and parents make informed decisions on how to fortify the breast milk based on the individual needs of the infant

<https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-diagnostic-test-aid-measuring-nutrients-breast-milk>

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## Wrapping Up Analysis

- Human milk analysis is a potentially useful tool for establishing an individualized fortification plan
- Understanding human milk composition and variability's provides an important tool for management of infant feeding
- Health care professionals should consider using analysis results in conjunction with clinical assessments (such as weight, growth and labs) to inform their discussions with parents and providers in creating a nutritional management plan
- Sensitivity when discussing results with families is critical

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## Conclusion: Changing the Culture

"As healthcare providers, we need to be believers that breastfeeding is worth the effort. Perhaps most importantly for us is to realize that human milk is not simply a food but rather a complex, human infant support system, a preventer of acute and chronic illness and disease."

Brenner, M. & Buescher, S. (2011) Breastfeeding: A Clinical Imperative. *Journal of Women's Health*, 20 (12), 1767-1773.



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## The King's Daughters Milk Bank

Thanks for sharing the health!  
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<b>Effects of Processing</b>			
	<b>Holder Method (HMBANA)</b>	<b>HTST (Prolacta)</b>	<b>Retort (Medolac)</b>
Protein (1.0 g/dL)	1.0 g/dL	0.8 g/dL	0.8 g/dL
Fat (4.3 g/dL)	3.4 g/dL	4.1 g/dL	3.0 g/dL
Carbs (7.3 g/dL)	7.2 g/dL	7.0 g/dL	7.0 g/dL
sigA (0.32 g/dL)	0.32 g/dL	0.38 g/dL	0.19 g/dL
Lactoferrin (1.15 g/dL)	1.45 g/dL	1.12 g/dL	0.5 f/dL
Lysozyme (0.05 g/dL)	0.03 g/dL	0.09 g/dL	0.05 g/dL
HMO's (8.05 g/dL)	12.58 g/dL	8.24 g/dL	6.64 g/dL

Meredith-Davis, et al (2018) Composition and Variation of Macronutrients, Immune Proteins, and Human Milk Oligosaccharides in Human Milk from Nonprofit and Commercial Milk Banks. Journal of Human Lactation, Vol. 34 (1) 125-129

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<b>CFU's and Processing Methods</b>			
	<b>Holder Method, HMBANA</b>	<b>VAT, Prolacta</b>	<b>Retort Sterilization, Medolac</b>
Eliminates bacteria and viruses	YES	YES	YES
Eliminates yeast, fungi, and mold	YES	YES	YES
Eliminates bacillus spores	NO	NO	YES
Perform post processing cultures	YES	YES	YES

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