Competitive Comparison

Not All Human Milk–Based Products Are Equal

We are the industry leaders in human milk–based nutrition because we make the most of human milk. You can see it in our patented manufacturing process which utilizes vat pasteurization, a process shown to retain higher levels of human milk's essential bioactive components when compared to other pasteurization methods.[1,2,3] Add in the highest quality and safety standards[4], evidence-based research[5], and a powerful system of support at all levels and it's clear that Prolacta provides an optimal human milk–based nutrition option.

Prolacta® BIOSCIENCE
Advancing the Science of Human Milk®

Table of Contents

How Prolacta Leads the Industry

Retention of Bioactive Components in Human Milk

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Greater retention of lactoferrin[1,2,6,7,8] Protects against infection through iron sequestration and lysing of bacterial cell walls; antioxidant and anti-inflammatory properties; decreases risk of late-onset sepsis and necrotizing enterocolitis in preterm infants	✓	✗
Greater retention of immunoglobulins[1,2,3,9] Protects against bacterial and viral infections by binding pathogens, neutralizing toxins and viruses, and blocking colonization and penetration of pathogens	✓	✗
Greater retention of lysozyme[2,3,10,11] Protects against infection by degrading the proteoglycan matrix of the bacterial cell wall; kills gram-positive bacteria, works synergistically with lactoferrin to kill gram-negative bacteria	✓	✗
Greater retention of α-lactalbumin[2,12] Aids in mineral absorption and healthy infant growth patterns; supports development of gastrointestinal tract and growth of beneficial microbes such as Bifidobacteria	✓	✗
Retains integrity of milk fat globule structure[10,13,14,15,16,17] Supports the structural and functional maturation of the gastrointestinal tract; helps to modulate the gut microbiota; provides antimicrobial, anti-inflammatory, and prebiotic functions; and promotes cognitive development	✓	✗

Safety & Testing Standards

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Donors undergo extensive medical and social screening, as well as blood testing[18,19]	✓	✓
Products follow U.S. Food and Drug Administration exempt infant formula regulations[20]	✓	?
Nutritionally standardized[18]	✓	✓
Microbiological screening of donor milk[19] Aerobic bacterial counts, *Bacillus cereus (BC), Escherichia coli, Salmonella, Pseudomonas,* coliforms, *Staphylococcus aureus,* yeast, mold, C emetic toxins and *Staphylococcus aureus* enterotoxin	✓	?
Stringent final container quarantine procedures[4] Final product quarantined until all data are reviewed, verified, and approved by Quality Assurance	✓	?
Milk tested for common drugs of abuse (marijuana, opiates, cocaine, benzodiazepines, oxycodone, amphetamines)[18,19,21]	✓	✓
Milk tested for adulterants (water, other types of milk)[18,19,21]	✓	✓
Low incidence of Bacillus cereus in incoming milk due to collection best practices[19,22,23]	✓	?
Breastmilk-to-donor DNA matching is confirmed to ensure every ounce of donated breastmilk comes from the qualified, tested, and approved donor[18]	✓	?
Milk tested for disease-causing viruses (HIV-1/2, HTLV-I/II, HBV, HCV, ZIKA, syphilis, tuberculosis, COVID-19)[18,19,21]	✓	?
Milk tested for nicotine[19]	✓	?
Milk tested for microbial contamination including Bacillus cereus at multiple points in the process including prior to processing[18,19,21]	✓	?
Maintains stringent raw milk quarantine procedures to ensure that only tested and verified batches of qualified milk are used to create products	✓	?

Final Product Testing & Objective, High-Quality Science

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Products evaluated in more than 20 peer-reviewed clinical studies[5]	✓	✗
Products referenced in published feeding protocols[24,25]	✓	✗
Studies showed: Lowered incidence of bronchopulmonary dysplasia (BPD)[26]	✓	✗
Lowered incidence and/or severity of retinopathy of prematurity (ROP)[26,27,28,29]	✓	✗
Adequate growth was achieved[30,31,32]	✓	✗
Reduced incidence of feeding intolerance[28]	✓	✗
Reduced hospital costs[28,33]	✓	✗
Shortened hospital stay by 4.5 days[28]	✓	✗
Lowered incidence[26,27] and evaluations[29] of late-onset sepsis	✓	✗
Associated with lower mortality and morbidity[26,34,35]	✓	✗
Full feeds achieved in at least 10 fewer days[28]	✓	✗

Final Product Testing & Objective, High-Quality Science

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Reduced total parenteral nutrition by 9 days[35]	✓	✗
Associated with long-term benefits including neurodevelopment, body composition, and metabolic outcomes[36,37,38,39]	✓	✗
Reduced incidence of necrotizing enterocolitis (NEC) and surgical NEC[35,40]	✓	✗

Medical, Scientific, & Financial Support to Help Our Hospitals

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Reliably delivering critical products Over 10 years of providing human milk–based nutritional products to neonatal intensive care units	✓	✗
Consultations available from healthcare professionals and research scientists Neonatologists, infectious disease physicians, nurse practitioners, nurses, dietitians, medical science liaisons, human milk scientists, medical researchers, and statisticians on staff and available for consultation	✓	?
Assistance with healthcare financial management Healthcare Financial Management Association (HFMA) – certified consultants available to customer hospitals	✓	✗
Healthcare provider peer support Nutrition Advisory Committee and Nursing Practice Advisory Council members from hospitals provide best practices, hold classes, and are available as resources Accredited continuing education programs	✓	✗
NICU staff support Detailed in-servicing provided by clinical sales specialists with implementation resources	✓	✗

Parent, Donor, & Community Support

	Prolacta Vat pasteurized; NOT homogenized	Others Retort sterilized & homogenized
Educating parents in the neonatal intensive care unit (NICU) with printed and online materials, along with the Peek-a-Boo ICU app	✓	?
Supporting more than 50 parent and professional organizations advocating on behalf of preterm and term infants throughout the world	✓	?
Donor counseling[41] Engaged online donor community that reports a high-level of donor satisfaction.	✓	?
Donors are offered a choice of remuneration or charitable donation for their time and effort[18,19,41]	✓	✗
Provided lactation support with team of Certified Lactation Education Counselors[41]	✓	✗
Supporting community organizations through product and monetary donations, including the Prolacta Bioscience Foundation that has more than 20 nonprofit organizations championing these important causes[42]	✓	✗

References

1 Liang N, Koh J, Kim BJ, Ozturk G, Barile D, Dallas DC. Structural and functional changes of bioactive proteins in donor human milk treated by vat-pasteurization, retort sterilization, ultra-high-temperature sterilization, freeze-thawing and homogenization. *Front. Nutr.* 2022. https://doi.org/10.3389/fnut.2022.926814

2 Meredith-Dennis L, Xu G, Goonatilleke E, Lebrilla CB, Underwood MA, Smilowitz JT. Composition and variation of macronutrients, immune proteins, and human milk oligosaccharides in human milk from nonprofit and commercial milk banks. *J Hum Lact.* 2018;34(1):120-129. https://doi.org/10.1177/0890334417710631

3 Lima HK, Wagner-Gillespie M, Perrin MT, Fogleman AD. Bacteria and bioactivity in holder pasteurized and shelf-stable human milk products. *Curr Dev Nutr.* 2017;1(8):e001438. https://doi.org/10.3945/cdn.117.001438

4 Standardized quality and safety from start to finish. Prolacta Bioscience. Accessed February 3rd, 2023. https://www.prolacta.com/en/about-us/quality-and-safety/

5 Clinical Evidence. Prolacta Bioscience. Accessed February 15th, 2023. https://www.prolacta.com/en/resources-evidence/

6 Manzoni P. Clinical studies of lactoferrin in neonates and infants: an update. *Breastfeed Med.* 2019;14(Suppl 1):S25-S27. https://doi.org/10.1089/bfm.2019.0033

7 Actor JK, Hwang SA, Kruzel ML. Lactoferrin as a natural immune modulator. *Curr Pharm Des.* 2009;15(17):1956-1973. https://doi.org/10.2174/138161209788453202

8 Safaeian L, Javanmard SH, Mollanoori Y, Dana N. Cytoprotective and antioxidant effects of human lactoferrin against H2O2-induced oxidative stress in human umbilical vein endothelial cells. *Adv Biomed Res.* 2015;4:188. https://www.advbiores.net/text.asp?2015/4/1/188/164010

9 Breedveld A, van Egmond M. IgA and FcαRI: pathological roles and therapeutic opportunities. *Front Immunol.* 2019;10:553. https://doi.org/10.3389/fimmu.2019.00553

10 Lönnerdal B. Bioactive proteins in human milk—potential benefits for preterm infants. *Clin Perinatol.* 2017;44(1):179-191. https://doi.org/10.1016/j.clp.2016.11.013

11 Zavaleta N, Figueroa D, Rivera J, Sánchez J, Alfaro S, Lönnerdal B. Efficacy of rice-based oral rehydration solution containing recombinant human lactoferrin and lysozyme in Peruvian children with acute diarrhea [published correction appears in *J Pediatr Gastroenterol Nutr.* 2008;46(1):121]. *J Pediatr Gastroenterol Nutr.* 2007;44(2):258-264. https://doi.org/10.1097/MPG.0b013e31802c41b7

12 Layman DK, Lönnerdal B, Fernstrom JD. Applications for α-lactalbumin in human nutrition. *Nutr Rev.* 2018;76(6):444-460. https://doi.org/10.1093/nutrit/nuy004

13 Salcedo J, Karav S, Le Parc A, et al. Application of industrial treatments to donor human milk: influence of pasteurization treatments, storage temperature, and time on human milk gangliosides. *npj Sci of Food.* 2018;2(5). https://doi.org/10.1038/s41538-018-0013-9

14 Lee H, Padhi E, Hasegawa Y, et al. Compositional dynamics of the milk fat globule and its role in infant development. *Front Pediatr.* 2018;6:313. https://doi.org/10.3389/fped.2018.00313

15 Weiser MJ, Butt CM, Mohajeri MH. Docosahexaenoic acid and cognition throughout the lifespan. *Nutrients.* 2016;8(2):99. https://doi.org/10.3390/nu8020099

16 Gallier S, Rowan A. Breastmilk composition and brain development. nzmp surestart. 2021. Accessed. February 15th, 2023. https://www.nzmp.com/content/dam/nzmp/pdfs/surestart/white-paper-breastmilk-composition-and-brain-development.pdf

17 Ozturk G, Paviani B, Rai R, Robinson R, Baller M, Nitin N, Barile D. Effects of Processing on Properties and Bioactivity of Milk Fat Globules in Donor Milk. Abstract presented at: N&G 2022. Proceedings of the 9th International Conference on Nutrition & Growth; 2022 Mar 17-19; Virtual Conference

18 Ni-Q. Accessed February 15th, 2023. https://www.ni-q.com/

19 LactaLogics. Accessed February 15th, 2023. https://lactalogics.com/

20 U.S. Food and Drug Administration. Exempt infant formulas marketed in the United States by manufacturer and category. Accessed February 15th, 2023. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category

21 Valentine CJ, Dumm M. Pasteurized donor human milk use in the neonatal intensive care unit. *NeoReviews.* 2015;16(3):e152-e159. https://doi.org/10.1542/neo.16-3-e152

22 Shimojima Y, Kodo Y, Soeda K, et al. [Prevalence of cereulide-producing bacillus cereus in pasteurized milk]. Shokuhin Eiseigaku Zasshi. 2020;61(5):178-182. Japanese. https://doi.org/10.3358/shokueishi.61.178

23 Demers-Mathieu V, Mathijssen G, Fels S, Chace DH, Medo E. Impact of vaccination during pregnancy and staphylococci concentration on the presence of Bacillus cereus in raw human milk. *J Perinatol.* 2020;40(9):1323-1330. https://doi.org/10.1038/s41372-019-0586-4

24 Beaver B, Carvalho-Salemi J, Hastings E, Ling H, Spoede E, Wrobel M, eds. Texas *Children's Hospital pediatric nutrition reference guide.* 12th ed. Houston, TX;2019:53.

25 Wight N, Kim JH, Rhine W, et al. Nutritional support of the very low birth weight (VLBW) infant. *California Perinatal Quality Care Collaborative.* 2018. February 15th, 2023. https://www.cpqcc.org/resources/nutritional-support-vlbw-infant#:~:text=The%202018%20update%20of%20the,nutritional%20outcomes%20for%20premature%20newborns

26 Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in Breastfeed Med. 2017;12(10):663] *Breastfeed Med.* 2016;11(2):70-74. https://doi.org/10.1089/bfm.2015.0134

27 O'Connor DL, Kiss A, Tomlinson C, et al. Nutrient enrichment of human milk with human and bovine milk–based fortifiers for infants born weighing <1250 g: a randomized clinical trial [published corrections appear in *Am J Clin Nutr.* 2019;110(2):529 and *Am J Clin Nutr.* 2020;111(5):1112] *Am J Clin Nutr.* 2018;108(1):108-116. https://doi.org/10.1093/ajcn/nqy067

28 Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. *J Perinatol.* 2016;36(3):216-220. https://doi.org/10.1038/jp.2015.168

29 Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive human milk diet. *Adv Neonatal Care.* 2019;19(6):460-467. https://doi.org/10.1097/ANC.0000000000000676

30 Huston R, Lee M, Rider E, et al. Early fortification of enteral feedings for infants <1250 grams birth weight receiving a human milk diet including human milk-based fortifier. *J Neonatal Perinatal Med.* 2020;13(2):215-221. https://doi.org/10.3233/NPM-190300

31 Huston RK, Markell AM, McCulley EA, Gardiner SK, Sweeney SL. Improving growth for infants ≤1250 grams receiving an exclusive human milk diet. *Nutr Clin Pract.* 2018;33(5):671-678. https://doi.org/10.1002/ncp.10054

32 Hair AB, Hawthorne KM, Chetta KE, Abrams SA. Human milk feeding supports adequate growth in infants ≤ 1250 grams birth weight. *BMC Res Notes.* 2013;6:459. https://doi.org/10.1186/1756-0500-6-459

33 Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. *Breastfeed Med.* 2012;7(1):29-37. https://doi.org/10.1089/bfm.2011.0002

34 Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med.* 2014;9(6):281-285. https://doi.org/10.1089/bfm.2014.0024

35 Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. *J Pediatr.* 2013;163(6):1592-1595.e1. https://doi.org/10.1016/j.jpeds.2013.07.011

36 Bergner EM, Shypailo R, Visuthranukul C, et al. Growth, body composition, and neurodevelopmental outcomes at 2 years among preterm infants fed an exclusive human milk diet in the neonatal intensive care unit: a pilot study. *Breastfeed Med.* 2020;15(5):304-311. https://doi.org/10.1089/bfm.2019.0210

37 Rahman A, Kase JS, Murray YL, Parvez B. Neurodevelopmental outcome of extremely low birth weight infants fed an exclusive human milk diet is not affected by growth velocity. *Breastfeed Med.* 2020;15(6):362-369. https://doi.org/10.1089/bfm.2019.0214

38 Visuthranukul C, Abrams SA, Hawthorne KM, Hagan JL, Hair AB. Premature small for gestational age infants fed an exclusive human milk-based diet achieve catch-up growth without metabolic consequences at 2 years of age. *Arch Dis Child Fetal Neonatal Ed.* 2019;104(3):F242-F247. https://doi.org/10.1136/archdischild-2017-314547

39 Hair, Amy B, Patel, Aloka L, et al. Neurodevelopmental outcomes of extremely preterm infants fed an exclusive human milk-based diet versus a mixed human milk+bovine milk-based diet: a multi-center study. *Journal of Perinatology.* 2022;42(11):1485-1488. https://doi.org/10.1038/s41372-022-01513-3

40 Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr.* 2010;156(4):562-567.e1. https://doi.org/10.1016/j.jpeds.2009.10.040

41 Donor resources. Prolacta Bioscience. Accessed February 15th, 2023. https://www.prolacta.com/en/donors/

42 Prolacta foundation. Prolacta Bioscience. Accessed February 15th, 2023. https://www.prolacta.com/en/about-us/our-foundation/

Prolacta® BIOSCIENCE
Advancing the Science of Human Milk®