TECHNICAL BULLETIN

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Topic: mOsm 48 Hour
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Prolacta Bioscience has previously provided data to establish that its products remain stable and safe for use after refrigeration for 48 hours. We have received numerous requests for data in regard to product that has been mixed with mothers milk. The purpose of this bulletin is to extend that information to include Prolact+ H²MF® that has been mixed with unpasteurized breast milk and left in the refrigerator for 48 hours.

In an experiment conducted under laboratory conditions Prolact+ H²MF was mixed with the appropriate amount of thawed, unpasteurized donor milk. The milk was immediately sampled after mixing and then placed in the refrigerator where it was maintained between 2° and 8°C and sampled at 24 and 48 hours and at one time point beyond 48 hours. The final time point was included in order to allow for claims to be made regarding the 48 hour time point. Each of the samples was tested for microbial growth and osmolality.

The results of the analyses showed that there was no untoward pathogenic growth over the test period nor was there any significant change in osmolality over time. (Table 1) in fact, for coliforms and total aerobic bacteria we saw a decrease over time as has previously been reported in the literature.[1,2]

Table 1 summary of assay results

Test Assay	**Summary of the Results**
Appearance / Visual Inspection	Met visual inspection, no visible particles or precipitate
Osmolality	No significant increase and did not exceed 400 mOsm/kg
E. coli	None detected
Coliform	Decreased in microbial counts over time
Total Aerobic Count (TAC)	Decreased in microbial counts over time
B. cereus	No increase over time

These data support the safety and stability of Prolact+ H²MF when mixed with unpasteurized breast milk and stored in the refrigerator for up to 48 hours. They also support the results of the study published by Chan et al. in 2007 showing that the natural antimicrobial properties of breast milk are not adversely affected by the addition of Prolact+ H²MF.[3]

1 Griffiths E, Humphreys J. Bacteriostatic effect of human milk and bovine colostrum on *Escherichia coli*: importance of bicarbonate. *Infect Immun*1977;15(2):396–401

2 Hernandez J, Lemons P, Lemons J, Todd J. Effect of storage processes on the bacterial growth-inhibiting activity of human breast milk. *Pediatrics*1979;63(4):597–601

3 Chan GM, Lee ML, and Rechtman DJ. "Effects of a human-milk derived human milk fortifier on the antibacterial actions of human milk" *Breastfeeding Medicine*. 2007, 2(4): 205-208.

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