

# UPDATE



## Probiotic Perspectives

### Refrigeration Helps Maintain Potency and Quality of Probiotic Products

Probiotics are delicate organisms that require appropriate handling to maintain maximum activity. In general, Klaire Labs® recommends that probiotics be refrigerated for long-term storage. Although probiotic strains vary in their sensitivity to heat, most studies show bacterial organisms lose viability over time at room temperatures. This can create significant product quality issues, especially in retail settings where probiotic products are often sold unrefrigerated. An industry study undertaken in the 1990s found that up to half of probiotic products purchased from retail stores contained significantly fewer live organisms than claimed on the label. According to the industry group conducting the study, one-quarter of the probiotics tested were not refrigerated at the time of purchase. A more recent 2003 review by an independent laboratory found that over one-third of commercial probiotic products tested contained less than 1% of the expected

number of viable organisms. While a number of factors can adversely affect probiotic viability, lack of refrigeration often plays a major role in the premature dieoff of organisms.

At Klaire Labs®, we conduct real-time stability studies on all our probiotic products to assess their long-term viability at both refrigerated and room temperatures. Data we've obtained from independent laboratory tests indicate our products maintain a relatively high degree of stability at room temperature for up to five months and then gradually begin to lose potency (see graph below). This suggests that while our probiotics require refrigeration to maintain viability over time, they do not quickly die off at room temperatures. Products may be taken out of the refrigerator for weeks or even months without a significant loss of viable organisms. Products shipped to customers with cold packs also retain excellent viability even if

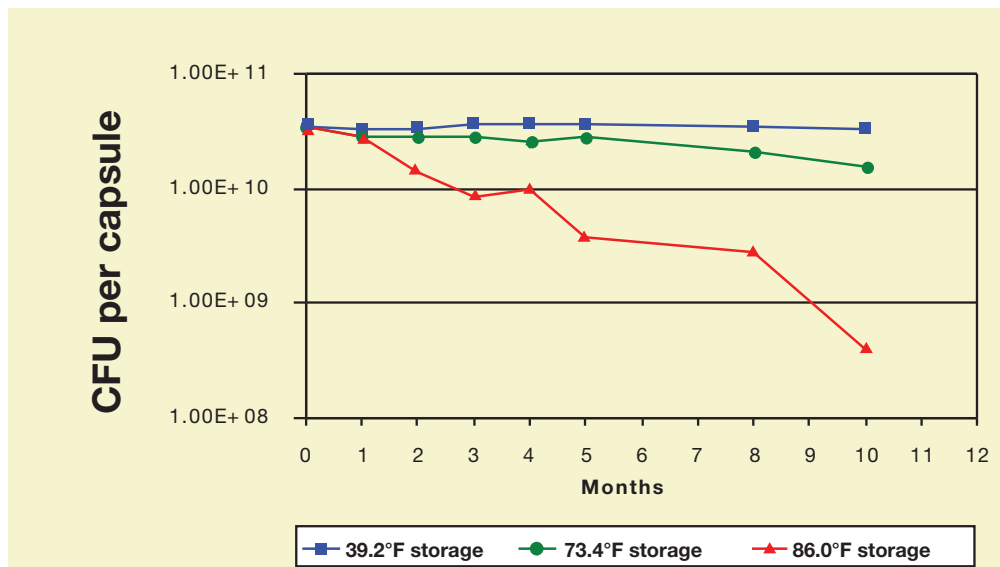
the cold packs are thawed and the product no longer feels cold to the touch at the time of arrival. To further ensure the potency of our products, we routinely formulate with "overages" so that even small losses of activity that may occur during shipping, handling, and storage are insignificant.

While cold-temperature storage clearly improves the long-term survival of probiotics, some manufacturers claim their products do not require refrigeration. Such claims should be regarded with caution unless the company can provide

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#### Independent Real-Time Probiotic Viability Study of Ther-Biotic® Complete

Temperature	Dec. 07	Jan. 08	Feb. 08	March 08	April 08	May 08	Aug. 08	Oct. 08
39.2°F (4°C) storage	33.9 billion	32.6 billion	33.3 billion	36.8 billion	36.2 billion	35.8 billion	34.9 billion	33.0 billion
73.4°F (23°C) storage	33.9 billion	28.8 billion	27.9 billion	28.5 billion	25.1 billion	27.5 billion	20.3 billion	15.3 billion
86.0°F (30°C) storage	33.9 billion	28.3 billion	13.7 billion	8.3 billion	10.0 billion	3.7 billion	2.8 billion	0.4 billion



independent, real-time stability data showing prolonged viability at room temperatures. In some instances, products purporting to be stable at room temperature contain spore-forming microbes such as *Bacillus coagulans* (often misidentified as *Lactobacillus sporogenes*), which because they are sold as spores, are stable at room temperature. However, they may not provide the same documented benefits as highly researched probiotics like *Lactobacillus* and *Bifidobacterium*. At Klaire Labs®, we use only probiotic species for which health benefits have been demonstrated in clinical studies. Our strains are genetically tested to ascertain their proper identity and grown in special dairy- and allergen-free media to ensure hypoallergenicity. We keep all of our probiotics under refrigeration in our warehouse until they are ready for cold-pack shipment to our customers. Finally, unlike some companies that provide potency information only at the time of manufacture, we guarantee our probiotic potencies through the expiration date stated on the label and have the stability data to back up our guarantee. We believe proper handling at every stage of the manufacturing, storage, and shipping process is just one way to assure our customers receive the highest quality probiotics available on the market.

References and further information available on request.