

## Are you in compliance with regulatory requirements?

### FDA Warning Letter

July 12, 2012

"Form FDA 483 Observation 2.A [April 10-25, 2012]: Your response states that a supplemental disinfectant efficacy study, using mold spores of in house isolates on various surfaces, will be performed and completed by [redacted]. We suggest that this proposed study be conducted as soon as possible."

### FDA Warning Letter

October 29, 2010

"...your firm does not perform challenge testing to the sterility media with environmental isolates from the environmental monitoring program."

### FDA Warning Letter

March 28, 2008

"Disinfectant effectiveness studies against representative microorganisms and/or specific in-house isolates were not conducted for cleaning agents used in your facility to disinfect production areas, including aseptic areas."

Our mission is simple . . .

To provide services and products in strict compliance with current Good Manufacturing Practices, in a timely manner, and at a straightforward and competitive price. We believe our role is not simply a supplier, but to partner with you as fellow microbiologists for the goal of meeting your needs.



**Cryologics, Inc.**  
*Specializing in Microbial Cryopreservation*

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Ottsville, PA 18942

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**Cryologics, Inc.**  
*Specializing in Microbial Cryopreservation*

*Cryologics converts your  
in-house isolates into the  
format required for  
compendial tests*

Cryologics.com

## CryoLC®

The “<100 cfu” format afforded by our CryoLC® products makes them ideally suited for many GMP microbiological applications, including:

- Media Growth Promotion
- Method Suitability (USP <61>, <62> and <71>)
- Validation of Microbial Recovery (USP <1227>)
- Analyst Qualification / Proficiency Testing
- Rapid Microbial Method (RMM) Qualification

# Units <sup>1</sup> /Set	Price <sup>2</sup>
50	\$3,890.00
100	\$4,990.00
Other	Quoted

<sup>1</sup> One “unit” is 1 mL of product, representing 10 aliquots, each delivering <100 cfu

<sup>2</sup> PA residents add 6% sales tax



## The advantages of CryoLC® and CryoHC® are clear!

- Lowest cost and turnaround time in the industry. Straightforward pricing is published on our website. Manufacturing is complete in just a few weeks.
- No “developmental”, “setup”, “organism”, or other non-refundable fees.
- No advance deposit required. Even shipping is included.
- Simply thaw, mix and aliquot. No rehydration or the use of more than one component, eliminating the risk of incidental contamination.
- No advance planning associated with preparing your organisms in-house. Eliminates resources needed for organism preparation. No repetition of work and delays due to “missed” titers.
- Minimal culturing from your submitted organism, ensuring less than five passages from the source culture.
- Demonstrated stability for several months.

## CryoHC®

The “10<sup>6</sup> - 10<sup>7</sup> cfu” format\* afforded by our CryoHC® products makes them ideally suited for many GMP microbiological applications, including:

- Disinfectant Efficacy Testing
- USP <51>, “Antimicrobial Effectiveness Testing”
- Sterilizing filter studies
- Biological Indicators (USP <55>)

\* We can also standardize your organism concentration to any range you specify (not to exceed a concentration of 10<sup>7</sup> - 10<sup>8</sup> cfu/0.1 mL)

# Units <sup>1</sup> /Set	Price <sup>2</sup>
25	\$4,890.00
50	\$5,990.00
Other	Quoted

<sup>1</sup> One “unit” is 1 mL of product, representing 10 aliquots, each delivering 10<sup>6</sup> - 10<sup>7</sup> cfu

<sup>2</sup> PA residents add 6% sales tax

**Contact Us!**  
**(610) 847-8781**

Visit our Website  
[www.Cryologics.com](http://www.Cryologics.com)

