



Leaders in Life Science and Technology

## TEST RESULT CERTIFICATE

<b>Sponsor</b>	Cyberbond	<b>Technical Initiation</b>	1/26/2007
<b>Address</b>	401 North Raddant Road Batavia, Illinois 60510	<b>Technical Completion</b>	1/28/2007
<b>Contact</b>	Kimberly McCall	<b>Report Date</b>	2/1/2007
<b>P.O. Number</b>	8686	<b>Project Number</b>	07-0317-N1

<b>Test Article</b>	Apollo 1701
<b>Lot/Batch #</b>	170325
<b>Study</b>	Agar Diffusion Test – ISO
<b>Comments</b>	None

**REFERENCES:** The study was conducted based upon the following references: ISO 10993-5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993-12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.


ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

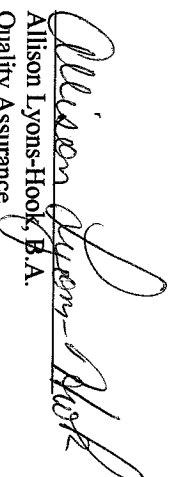
**GENERAL PROCEDURE:** The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article was determined. The monolayer was protected from mechanical damage, while allowing diffusion of leachable chemicals from the test article, with a layer of agar stained with a vital dye (neutral red). The test article was applied directly to the surface of the agar, in triplicate. Positive (Buna-N-Rubber) and negative (Negative Control Plastic) control articles were prepared to verify the proper functioning of the test system. The cultures were incubated at  $37 \pm 1$  °C, in a humidified atmosphere containing  $5 \pm 1\%$  carbon dioxide, for 48 hours. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No reactivity) to Grade 4 (Severe reactivity). The test article met the requirements of the test if none of the cultures exposed to the article showed greater than a Mild Reactivity (Grade 2).

**RESULTS:** No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article. No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the negative control article at the 48 hour observation. Moderate signs of reactivity (Grade 3) were observed for the positive control article at the 48 hour observation.

**CONCLUSION:** The test article is considered non-cytotoxic and meets the requirements of the Agar Diffusion Test, ISO 10993-5 guidelines.

### AUTHORIZED PERSONNEL:

  
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