Executive Summary

Microbial Testing

1.0 Objective

1.1 The objective of this summary is to briefly delineate the scope of testing that has been conducted to assure the safety and effectiveness of the Theraworx platform.

2.0 Scope

2.1 The scope of this report shall cover the original testing completed as part of the patented process (2002), as well as all subsequent antimicrobial and biocompatibility testing recently conducted.

3.0 References

3.1 AATCC Method 100: Antibacterial Finishes on Textile Materials: Assessment of

3.2 ISO/DIS 10993: Biological evaluation of Medical Devices - Part 1: Evaluation and Testing

4.0 Attachments

4.1 Test reports available upon request.

5.0 Definitions

5.1 Theraworx - A Patented, pH and Hygiene Management System.

6.0 Testing Data

6.1 Original Testing

6.1.1 Antimicrobial Activity Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on January 15, 1998.

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
E. Coli	11229	2.32×10^3	>99.9%
S. aureus (MRSA)	33591	1.06×10^3	>99.9%
C. albicans	10231	1.06×10^4	>99.9%

6.1.2 Antimicrobial Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on June 12, 2000

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
E. faecalis	29212	1.36×10^4	>99.9%
S. aureus (MRSA)	33591	6.6×10^4	>99.9%

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6.1.3 Antiviral Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on July 3, 2000.

Test Organism	Initial Inoculum	Percent Reduction
Influenza A	$1.0 \times 10^{4.5}$	>99.9%
Herpes Simplex	$1.0 \times 10^{4.5}$	>99.9%

6.2 Antimicrobial Testing

6.2.1 AATCC Method 100 Antimicrobial Testing

Testing was conducted by Apptec Laboratories on behalf of Avadim, LLC between September 5, 2007 through June 12, 2008

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
C. albicans	10231	1.1×10^5	>99.9%
M. luteus	49732	1.1×10^5	>99.9%
C. ammoniagenes	6872	1.7×10^5	>99.9%
S. epidermidis	12228	1.3×10^5	>99.9%
S. aureus (MRSA)	33591	1.3×10^5	>99.99%
Acinetobacter baumannii	15308	1.4×10^6	>99.99%
E. faecalis	51575	1.4×10^6	>99.99%
E. coli	8739	1.6×10^6	>99.99%
P. aeruginosa	9027	1.2×10^6	>99.99%
C. difficile	9689	2.4×10^7	>99.99%
Carbapenem resistant E. Coli	A15667	7.8×10^6	>99.9%
Klebsiella pneumoniae Carbapenem resistant	A15666	7.8×10^4	99.30%

6.2.2 Antimicrobial Efficacy Duration Study

Testing was conducted by St. John's Research Institute on behalf of Avadim, LLC on November 14, 2007. This study was based upon a one-time application of collegen and re-inoculated at various time periods.

Time	Test Organism	Initial Inoculum	Percent Reduction
15 minutes	S. aureus (MRSA)	3.0×10^5	>99%
30 minutes	S. aureus (MRSA)	3.0×10^5	>99%
60 minutes	S. aureus (MRSA)	3.0×10^5	>99%
120 minutes	S. aureus (MRSA)	3.0×10^5	>99%
180 minutes	S. aureus (MRSA)	3.0×10^5	>99%

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6.3 Biocompatability Testing

6.3.1 Outline

Theraworx has been subject to *in vitro* and *in vivo* biocompatibility testing (ISO Intracutaneous Reactivity Test, ISO Acute Systemic Injection Test, ISO Guinea Pig Maximization Sensitization Test, and MEM-Elution using L-929 Mouse Fibroblast Cells(ISO) (Cytotoxicity)). These tests support the safe use of TheraworxTM in contact with breached or compromised skin.

6.3.2 MEM Elution Using L-929 Mouse Fibroblast Cells (ISO) (Cytotoxicity)

6.3.1.1 Reference:	ISO 10993-1
6.3.1.2 Report No.	66958
6.3.1.3 Date Tested:	November 9,2007
6.3.1.4 Conducted By:	Apptec Laboratories
6.3.1.5 Results:	Test was considered valid as the control results were within acceptable parameter. The test article PASSED and is considered NON-TOXIC under the test conditions employed.

6.3.3 ISO Intracutaneous Reactivity Test

6.3.2.1 Reference:	ISO 10993-1
6.3.2.2 Report No.	66959
6.3.2.3 Date Tested:	December 10,2007
6.3.2.4 Conducted By:	Apptec Laboratories
6.3.2.5 Results:	The test article is considered a NON-IRRITANT.

6.3.4 ISO Acute Systemic Injection Test

6.3.3.1 Reference:	ISO 10993-1
6.3.3.2 Report No.	101611
6.3.3.3 Date Tested:	February 11,2008
6.3.3.4 Conducted By:	Apptec Laboratories
6.3.3.5 Results:	No potential toxic effects as a result of a single-dose systemic injection were observed; test article PASSED the test.

6.3.5 ISO Guinea Pig Maximization Sensitization Test

6.3.4.1 Reference:	ISO 10993-1
6.3.4.2 Report No.	101612
6.3.4.3 Date Tested:	March 13, 2008
6.3.4.4 Conducted By:	Apptec Laboratories
6.3.4.5 Results:	None of the test animals challenged with the test article extracts were observed with a sensitization response greater than "0". Test article did NOT elicit a sensitization response.

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