Executive Summary

Microbial Testing

1.0 Objective

1.1 Efficacy Data of Theraworx Protect on leading pathogens, bacteria, viruses, yeast and Fungi.

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 Pathogens

Testing was conducted by Bioscience Labs - Nelson Laboratories – Bozeman, Montana on June 9, 2017.

Test Organism	ATCC No.	Test Number	Percent Reduction
Acinetobacter baumannii	BAA-1605	1611494-201	>99.9999%
Enterobacter aerogenes	13048	1611494-201	>99.9999%
Enterococcus faecalis	51575	1611494-201	>99.9999%
Escherichia coli	11229	1611494-201	>99.9%
Haemophilus influenzae	19418	1611494-201	>99.9999%
Klebsiella pneumoniae DR	BAA-1705	1611494-201	>99.9999%
Pseudomonas aeruuginosa	15442	1611494-201	>99.9999%
Pseudomonas aeruuginosa	MDR 030116Pa5	1611494-201	>99.9999%
Staphylococcus aureus MRSA	33591	1611494-201	>99.9999%
Staphylococcus epidermidis	12228	1611494-201	>99.9999%
Staphylococcus haemolyticus	29970	1611494-201	>99.9%
Staphylococcus hominis	700236	1611494-201	>99.9999%
Streptococcus pneumoniae	49619	1611494-201	>99.9999%
Streptococcus pyogenes	19615	1611494-201	>99.9999%
Carbapenem resistant E. Coli	A15667	AJIC2015 Wiemken	>99.9%
Klebsiella pneumoniae Carbapenem resistant	A15666	AJIC2015 Wiemken	>99.30%

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6.1.3 Yeast and Fungi

Testing was conducted by Bioscience Labs - Nelson Laboratories – Bozeman, Montana on June 9, 2017.

Test Organism	ATCC No.	Test Number	Percent Reduction
Candida albicans	10231	1611494-201	>99.9999%
Fusarium solani	36031	1611494-201	>99.9999%
Candida albicans	ASTM82783-17	1703130-201	>99.9999%

6.1.4 Viruses

Evaluation of one test article for virucidal properties based upon the ASTM E1052-20 Method on January 12, 2023

Testing was conducted by Neslon Laboratories Bozeman, LLC

Test Organism	ATCC No.	Test Number	Percent Reduction
Haemophilus influenzae	19418	1611494-201	>99.9999%
Respiratory syncytial virus strain Long (RSV)	VR-26	2211575-402	>99.99%

This study evaluated virucidal properties of one test article when challenged with Respiratory Syncytial Virus (ATCC #VR-26). The testing was based upon ASTM E1052-20, Standard Practice to Assess the Activity of Microbicides against Viruses in Suspension.

6.2 Antimicrobial Efficacy Duration Study

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

Time	Test Organism	Percent Reduction
15 minutes	S. aureus (MRSA)	>99%
30 minutes	S. aureus (MRSA)	>99%
60 minutes	S. aureus (MRSA)	>99%
120 minutes	S. aureus (MRSA)	>99%
180 minutes	S. aureus (MRSA)	>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 Theraworx® 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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