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FINAL REPORT

TITLE: MODIFIED DRAIZE-95 TEST

STUDY REPORT NUMBER: HMR-MDT-02-04-20-[redacted]

Study Completion Date: 07 AUG 2020

Test Material: Powder Free Nitrile Examination Aloe Vera Gloves - Green

STUDY SPONSOR	TESTING FACILITY
[redacted]	**MAKMAL BIOSERASI & KLINIKAL HEALTHMEDIC RESEARCH SDN BHD** Lot B-G-34 & 35, Pangsapuri Sri Penara, Jalan Sri Permaisuri 1, Bandar Sri Permaisuri, Cheras 56000, KUALA LUMPUR

Study Director : Dr. Saadiah Sulaiman

Clinical Investigators : Dr. Sharifah Ismail

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- It contains 31 pages (not inclusive of this page).
- This test report concerns only the product being tested.

'MODIFIED DRAIZE-95' TEST IN NORMAL INDIVIDUAL (HUMAN STUDY)

	Signatures
Study Director/Principal Investigator	
Dr. Saadiah Sulaiman Dermatologist MBBCh (Dub), MMED (UKM)	 **Date:** 07/08/2020
Clinical Investigator	
Dr. Sharifah Ismail MD (UISU), Indonesia	 **Date:** 07/08/2020
Sponsor	
[redacted]	**Date:**

'MODIFIED DRAIZE-95' TEST IN NORMAL INDIVIDUAL (HUMAN STUDY)

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SUMMARY

'MODIFIED DRAIZE-95' TEST IN NORMAL INDIVIDUAL (HUMAN STUDY)

Study completion date : 07/08/2020
Study reference number : ITM-MDT-021-01-1-20(04-20)
Study report number : [redacted]
Conditions of use : Neat
Test material : Powder Free Nitrile Examination Aloe Vera Gloves - Green
Supplier Batch number : Y19346F25B01

1. OBJECTIVES

1. To evaluate whether residual chemical additives at a level that may induce Type IV allergy in the unsensitized general user population are present in a finished rubber containing medical device, **Powder Free Nitrile Examination Aloe Vera Gloves - Green**.

2. To meet requirements for claim: This product demonstrated reduced potential for sensitizing users to chemical additives as described in Guidance for Industry and FDA Staff - Medical Glove Guidance Manual[6]. Supporting Test Data: A negative skin sensitization test (Modified Draize-95 Test) on a minimum of 200 non-sensitized human subjects.

2. EXPERIMENTAL PROCEDURE

Study subjects : Non-sensitized Adult Volunteers
Number of subjects : 210
Age : 18 to 65 years old
Experimental starting date : 04th February 2020
Experimental completion date : 27th June 2020
Ethics approval number : 1) Islamic University of Gaza
470/10/IUG
: 2) Healthmedic Research Ethics Committee (HMREC)
HMREC-HMR-04-2020

Procedure

The inner and outer surface of the rubber glove was tested on the human skin. A total of 210 human subjects were patched with inner and outer surface of rubber glove. The study was conducted in two stages. The second stage was conducted after the first stage has shown that the test product does not indicate a potential for inducing severe dermal irritation and does not show sensitization capability.

2.1 Induction Phase

Samples of the test material, both the inner and outer surface with minimum size of 2 cm by 2 cm each, was applied to each test subject in the study. The test material was patched on to the upper back area and continuously secured on the edges with a nonreactive adhesive tape, micropore* whilst ensuring the complete occlusion of the patch.

Control materials were also applied in a similar manner.

The induction phase of the test includes application of ten patches of test material on each Monday, Wednesday, and Saturday. The test material was removed and replaced with a new one at the same site every 48 hours for a total of ten changes. Patches applied on Saturday were removed on Monday.

2.2 Rest Period

At the end of the three-week induction period, the tenth test material was removed and no further test material were applied to the test subjects for the following 2 to 3 weeks, until the challenge patches were applied.

2.3 Challenge Phase

Two samples of the same test material, both the inner and outer surface with minimum of 2 cm by 2 cm in size were applied consecutively to a virgin site for 48 hours each. The test site was evaluated for reaction at the time of each patch removal and again 2 to 4 days after removal of the second patch.

3. SELECTION OF SUBJECT / STUDY POPULATION

The test was completed on non-sensitized adult human subjects, 207 (for inner surface) and 206 (for outer surface). This sample size, with all negative results, provides more than 95% confidence that the chemical sensitization potential of the tested rubber containing medical device in the user population is expected to be less than 1.5%.

4. RESULT

A total of 210 human subjects were patched with inner and outer surface of rubber glove.

Inner surface

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Three subjects were discontinued (two subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 207 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.12 ± 11.46 years). One hundred and four subjects were female (50.24%) and 103 subjects were male (49.76%).

All these 207 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase.

Outer surface

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 206 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.17 ± 11.47 years). One hundred and four subjects were female (50.49%) and 102 subjects were male (49.51%).

All these 206 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase.

5. INTERPRETATION OF RESULTS

The study that was completed on non-sensitized adult human subjects, 207 (for inner surface) and 206 (for outer surface) giving all negative results, hence provides more than 95% confidence that the chemical sensitization potential of the tested rubber containing medical device in the user population is expected to be less than 1.5%.

6. CONCLUSION

There was no clinical evidence of the presence of residual chemical additives at the level that may induce Type IV allergy in the unsensitized general user population in the tested material, **Powder Free Nitrile Examination Aloe Vera Gloves - Green.**

The skin sensitization test ('Modified Draize-95' Test) of this medical device, **Powder Free Nitrile Examination Aloe Vera Gloves - Green**, tested on 207 non-sensitized human subjects with inner surface and tested on 206 non-sensitized human subjects with outer surface are negative, hence meeting the requirements for the claim: This product demonstrated reduced potential for sensitizing users to chemical additives as described in Guidance for Industry and FDA Staff - Medical Glove Guidance Manual[6].

FINAL REPORT

1.0	**MANUFACTURER OF TEST MATERIAL**	
1.1	**Name**	: [redacted]
1.2	**Address**	: [redacted]
1.3	**Study report number**	: [redacted]
2.0	**DETAILS OF TEST MATERIAL**	
2.1	**Name of test material**	: Powder Free Nitrile Examination Aloe Vera Gloves - Green
2.2	**Intended used of test material**	: A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner
2.3	**Test material references**	: [redacted]
2.4	**Study reference number**	: [TM-MDT-02]-01-1-20 (04-20)
2.5	**Batch/Lot number**	: Y19346F25B01
2.6	**Date test material receive**	: 24/01/2020
2.7	**Characteristic**	: Glove
2.8	**Manufacturing date**	: 12/12/2019
2.9	**Expiry date**	: N/A
2.10	**Physical description**	: Solid
2.11	**Colour**	: Green
2.12	**Quantity**	: 300 pcs
2.13	**Storage requirement**	: Ambient
2.14	**Solubility**	: N/A
2.15	**Condition of use**	: Neat
2.16	**Experimental starting date**	: 04th February 2020
2.17	**Experimental completion date**	: 27th June 2020

3.0 CENTRE FOR CONDUCT OF TEST AND RELEVANT INFORMATION

3.1	**Centre of test**	
3.1.1	**Name**	: Makmal Bioserasi dan Klinikal
3.1.2	**Address**	: Lot B-G-34, Pangsapuri Sri Penara, Jalan Sri Permaisuri 1, Bandar Sri Permaisuri, Cheras 56000, Kuala Lumpur
3.1.3	**Name**	: Islamic University of Gaza (IUG)
3.1.4	**Address**	: Islamic University of Gaza, P.O. Box 108, Rimal, Gaza Strip, Palestine.

3.2 Project staff

3.2.1 Study Director / Principal Investigator:
Dr Saadiah Sulaiman,
MBBCh (Dub), MMED (UKM)

3.2.2 Clinical Investigator:
Dr Sharifah Ismail
MD (UISU), Indonesia
Dr. Said S. S. Al Ghora
Dr Amal Al Maqadma

3.2.3 Study Personnel
Noramini Binti Zainuri

3.2.4 Quality Assurance Personnel
Norfarah Izzaty Razaly

3.3 Address of correspondence

3.3.1 [redacted]

4.0 NAME OF TEST:
'Modified Draize-95' Test in normal individual (Human Study)

4.0.1 Introduction
There are three distinctive types of adverse reactions to rubber that differ in their mechanisms of induction and resulting clinical manifestations. These reactions include irritation, delayed hypersensitivity (Type IV allergy) and immediate hypersensitivity (Type I allergy). Type IV allergy is a cell-mediated immunological reaction resulting in allergic contact dermatitis that develops 1 to 4 days after the exposure. Type IV allergy is predominantly induced by the residual chemical additives (thiazoles, thiurams and carbamates) on the finished rubber containing medical devices. Type IV allergic reactions to rubber containing medical devices represent serious problems as the exposure of sensitized individuals to rubber medical devices may be career-threatening.

With reference to the proposal derived from the guidance document *"Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber Products" available* on the World Wide Web at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073792.htm#e_2_4.'

This test is used for:
Claim: Low Dermatitis Potential
This product demonstrated reduced potential for sensitizing users to chemical additives.
Warning: Do not use this product if you have a known allergy to natural rubber protein or chemical additives.

Supporting Test Data
A negative skin sensitization test (Modified Draize-95 Test) on a minimum of 200 non-sensitized human subjects.

4.0.2 Study Protocol
This study protocol is based on the
1. "*Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber Products*" document (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073792.htm#e_2_4)
2.*Medical Glove Guidance Manual* (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm428191.pdf) with some modification.
3. ASTM: D6355-07, Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves. Current edition reapproved 2017.

4.1 **Objectives**

1. To evaluate whether residual chemical additives at the level that may induce Type IV allergy in the unsensitized general user population are present in a finished rubber containing medical device, **Powder Free Nitrile Examination Aloe Vera Gloves - Green**.

2. To meet requirements for the claim: This product demonstrated reduced potential for sensitizing users to chemical additives. As describe in Guidance for Industry and FDA Staff - Medical Glove Guidance Manual[6]. (Supporting Test Data: A negative skin sensitization test (Modified Draize-95 Test) on a minimum of 200 non-sensitized human subjects).

4.2 **Materials**

Source: The test material was received from the Sponsor:

1. In the form of final product labeled as: **Powder Free Nitrile Examination Aloe Vera Gloves - Green**: tested for both the inner and outer surface.
2. In the form of rubber glove as control labeled as: Textured, Powder Free Latex Gloves.

Identification: The tested product was identified using information provided by the sponsor, including the product name, lot number, expiration date, and storage conditions.
Sample Description: The observable physical properties of the tested product, the batch or lot number, stability and composition information were provided by the Sponsor.
Analysis: The Sponsor is responsible for all analytical work required to characterize the test material, to validate its stability and to ensure that the product comply with the prerequisites for conduct of human studies.
Storage: The test material was stored at ambient room temperature and humidity unless otherwise specified by the Sponsor.

4.3 **Selection of Subject / Study Population**

The test was completed on a minimum of 200 non-sensitized adult human subjects. This sample size, with all negative results, provides more than 95% confidence that the chemical sensitization potential of the rubber containing medical device in the user population is expected to be less than 1.5%.

Test Subjects

A minimum of 200 healthy adult subjects.

4.3.1 **Admission / Recruitment Criteria**

The procedures for recruitment involve thorough explanation about the purpose and conduct of the study and about any possible risk or consequence resulting from their participation of the study. Each subject read and countersigned the consent form prior to recruitment into the study.
A total of 210 non-sensitized adult human subjects were enrolled into the study. The selection of the subjects was made according to the inclusion and exclusion criteria below:

4.3.2 **Inclusion Criteria**

a. The test subjects are normal volunteers who have documented informed consent and have not participated in other voluntary testing for at least 30 days.
b. Age of the test subjects ranged from 18 to 65 years.
c. Efforts are made to provide racial and gender diversity of the test subjects that reasonably reflects the general user population in the US.

4.3.3 Exclusion Criteria

a. The test subjects with any visible skin disease that might be confused with skin reactions caused by the test material.
b. The test subjects with any indication of existing Type I allergy to natural rubber proteins.
c. The test subjects who have used corticosteroids either systemically or topically on the potential test site two weeks before testing.
d. Test subjects who have received endogenous or exogenous immunosuppressive treatment (or prolonged sun exposure).
e. All subjects who are pregnant or become pregnant during the study.
f. All lactating women.

4.4 Study Procedure

The inner and outer surface of the rubber glove was tested on the human skin. A total of 210 human subjects were patched with inner and outer surface of rubber glove. The study was conducted in two stages. The second stage was conducted after the first stage has shown that the test product does not indicate a potential for inducing severe dermal irritation and does not show sensitization capability.

4.4.1 Induction Phase

Samples of the test material, both the inner and outer surface with minimum size of 2 cm by 2 cm each, was applied to each test subject in the study. The test material was patched on to the upper back area and continuously secured on the edges with a nonreactive adhesive tape, micropore* whilst ensuring the complete occlusion of the patch.

Control materials were also applied in a similar manner.

The induction phase of the test includes application of ten patches of test material on each Monday, Wednesday, and Saturday. The test material was removed and replaced with a new one at the same site every 48 hours for a total of ten changes. Patches applied on Saturday were removed on Monday.

Any and all skin reactions during this induction phase were recorded. Subjects that developed reaction that occurred to an initial induction test patch, were considered as a presensitized individual. Reactions observed after placement of the second patch in the induction phase was generally considered an irritation.

Note: For subjects who develop a positive reaction (a score value of 1.5) to chemicals or show signs of irritation after patch applications, further patching on those individuals are stopped. After a minimum of 3 weeks of rest, these individuals receive a challenge patch to confirm the observed reaction as either preexisting sensitivity or irritant reaction. When a local irritation caused by the occlusion material occurs, occlusion tape would be replaced with the non-irritating one, and the induction patching would be further continued.

*supplied by 3M Pharmaceuticals

4.4.2 **Rest Period**
At the end of the three weeks induction period, the tenth test material was removed and no further test material were applied to the test subjects for the next two to three weeks, until the challenge patches were applied.

4.4.3 **Challenge Phase**
Two samples of the same test material, both the inner and outer surface with minimum of 2 cm by 2 cm in size were applied consecutively to a virgin site for 48 hours each. The test site was evaluated for reaction at the time of each patch removal and again 2 to 4 days after removal of the second patch.

4.5 **Adverse Events**
All adverse events observed during the study period were reported. All findings were recorded in the case record form.

4.5.1 **Efficacy Measures**
All volunteers were given clinic and doctor contact number. This would enable them to contact the doctor in charge should there be any problems encountered throughout the study period.

4.6 **Scoring Criteria**
4.6.1 **Patch Testing Diagnostic criteria** are based on standard scoring of the North American Contact Dermatitis Research Group (NACDRG) (" Am. J. Contact Dermatitis" 2: 122-129, 1991).

Table 1a &1b: Scoring Criteria - The intensity of reactions were scored according to the following criteria

Table 1a

Basic Score	Description
0	No visible reaction
0.5	Doubtful or negligible erythema reaction
1.0	Mild or just perceptible macular erythema reaction in a speckled/follicular, patchy or confluent pattern (slight pinking)
2.0	Moderate erythema reaction in a confluent pattern (definite redness)
3.0	Strong or brisk erythema reaction that may spread beyond the test site

Table 1b

Supplemental scores	Description	Label
0.5	Edema	E
0.5	Papules	P
0.5	Vesicles	V
0.5	Bullae	B

The supplemental scores were added to the basic score, if the reactions include the described signs. The final score is the sum of basic and supplemental score values.

During the induction phase of the study, further patching would be stopped on subjects who develop positive reaction (a score value of 1.5) to chemical or shows signs of irritation after patch application.

After a minimum of 3 weeks of rest, these individuals would receive a challenge patch to confirm observed reaction as either preexisting sensitivity or irritant reaction. All such cases were recorded and reported in addition to the initial number of test subjects in the panel group.

Note: In order to qualify for the claim of a reduced sensitization potential, all the subjects completing the study should exhibit a score value of no more than 1.5 based on the scoring criteria describe above.

The individuals who were identified as either presensitized to rubber chemicals or presenting as irritant reactions, would be excluded from the statistical evaluation. However, the data from each such case would be recorded and reported in addition to the data for the all non-sensitized test individuals completing the test.

5.0 RESULTS

A total of 210 human subjects were patched with inner and outer surface of rubber glove.

5.1 Inner surface

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Three subjects were discontinued (two subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 207 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.12 ± 11.46 years). One hundred and four subjects were female (50.24%) and 103 subjects were male (49.76%).

All these 207 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase. (See Table 2a, Table 2b and Table 6a).

Table 2a: Final Score of the skin reaction induced by the test patches during the challenge phase in 207 non sensitized subjects (inner surface).

Total score	Number of subjects
Score less than 1.5	207
Score more than 1.5	0

Table 2b: Scoring of skin reactions induced by the test patches (inner surface) during the Induction and Challenge phase in 207 non-sensitized subjects.
Test material: **Powder Free Nitrile Examination Aloe Vera Gloves - Green** (inner surface).

	Induction Phase											**Challenge Phase 48 hours**			
Day	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	207	207	207	207	207	207	207	207	207	207	207	207	207	207	207
0	207	207	203	203	206	207	205	207	205	207	205	207	207	205	207
0.5	0	0	2	1	1	0	0	0	1	0	1	0	0	2	0
1	0	0	2	3	0	0	2	0	1	0	1	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

During the course of study, three subjects were discontinued (two subjects due to skin irritation reaction and one subject due to poor compliance). See Table 6b.

5.2 **Outer surface**

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 206 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.17 ± 11.47 years). One hundred and four subjects were female (50.49%) and 102 subjects were male (49.51%).

All these 206 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase. (See Table 3a, Table 3b and Table 7a).

Table 3a: Final Score of skin reactions induced by the test patches during the challenge phase in 206 non sensitized subjects (outer surface).

Total score	Number of subjects
Score less than 1.5	206
Score more than 1.5	0

Table 3b: Scoring of skin reactions induced by the test patches (outer surface) during the Induction and Challenge phase in 206 non-sensitized subjects.
Test material: **Powder Free Nitrile Examination Aloe Vera Gloves - Green** (outer surface).

	Induction Phase											**Challenge Phase 48 hours**			
Day	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	206	206	206	206	206	206	206	206	206	206	206	206	206	206	206
0	206	206	203	203	204	206	205	206	205	205	204	206	206	204	206
0.5	0	0	2	1	2	0	0	0	1	1	1	0	0	2	0
1	0	0	1	2	0	0	1	0	0	0	1	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

During the course of study, four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance). See Table 7b.

5.3 Control item 1

Textured, Powder Free Latex Gloves

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 206 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.17 ± 11.47 years). One hundred and four subjects were female (50.49%) and 102 subjects were male (49.51%).

All these 206 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase. (See Table 4a and Table 4b).

Table 4a: Final Score of the skin reaction induced by the control test patches during the challenge phase in 206 non sensitized subjects.

Total score	Number of subjects
Score less than 1.5	206
Score more than 1.5	0

Table 4b: Scoring of skin reactions induced by the control test patches during the Induction and Challenge phase in 206 non-sensitized subjects.

	Induction Phase											**Challenge Phase 48 hours**			
Day	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	206	206	206	206	206	206	206	206	206	206	206	206	206	206	206
0	206	206	205	204	204	205	206	206	206	206	206	206	205	205	204
0.5	0	0	1	1	2	0	0	0	0	0	0	0	1	1	2
1	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

During the course of study, four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance).

5.4 **Control item 2**
Filter paper

A total of 210 subjects, 150 subjects, Caucasian (71.42%), 30 subjects, Afro Caribbean (14.29%) and 30 subjects, Asiatic (14.29%) were recruited into the study. Four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance). Hence, 206 subjects completed the two stages of the study. Age range of the study subjects were between 18 – 65 years (mean 29.17 ± 11.47 years). One hundred and four subjects were female (50.49%) and 102 subjects were male (49.51%).

All these 206 subjects had a final score of not more than 1.5 during the induction phase and the challenge phase. (See Table 5a and Table 5b).

Table 5a: Final Score of the skin reaction induced by the control test patches during the challenge phase in 206 non sensitized subjects.

Total score	Number of subjects
Score less than 1.5	206
Score more than 1.5	0

Table 5b: Scoring of skin reactions induced by the control test patches during the Induction and Challenge phase in 206 non-sensitized subjects.

	Induction Phase											**Challenge Phase 48 hours**			
Day	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	206	206	206	206	206	206	206	206	206	206	206	206	206	206	206
0	206	206	206	206	206	206	206	206	206	206	206	206	206	205	205
0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

During the course of study, four subjects were discontinued (three subjects due to skin irritation reaction and one subject due to poor compliance).

All subjects had a final score of not more than 1.5 during induction phase and the challenge phase.

The percentage of positive reaction during the induction phase and the challenge phase for the test material and the control sample is summarized in Table 5c below.

Table 5c: Summary of percentage of positive reaction during the induction phase and the challenge phase for the test material and the control sample.

Description	Number of subjects	Percentage of positive reaction in non sensitized subjects	
		Induction	Challenge
Test sample 1. Powder Free Nitrile Examination Aloe Vera Gloves - Green (inner surface)	207	0%	0%
2. Powder Free Nitrile Examination Aloe Vera Gloves - Green (outer surface)	206	0%	0%
Negative control 1. Control sample: Textured, Powder Free Latex Gloves	206	0%	0%
2. Filter paper	206	0%	0%

Table 6a: Modified Draize-95 Test Tabulation of scoring: **Powder Free Nitrile Examination Aloe Vera Gloves - Green** (*Inner surface*) - Basic and Supplemental Score of cutaneous reactions that occurred during the Induction and Challenge Phase (207 subjects).

No.	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	M1	F	43	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	M2	F	50	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	M3	F	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	M4	F	46	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	M5	F	42	III	0	0	0	0	**0.5**	0	**1.0**	0	**0.5**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	M6	F	28	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	M7	F	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	M8	F	22	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	M9	F	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	M10	F	52	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	M11	F	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	M12	F	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	M13	F	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	M14	F	26	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	M15	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	M16	F	49	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	M17	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	M18	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	M19	F	44	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	M20	F	35	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	M21	F	41	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	M22	F	42	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	M23	F	27	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	M24	F	49	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0
25	M25	F	22	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	M26	F	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	M27	F	36	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	M28	F	22	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	M29	F	52	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0
30	M30	M	21	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	G1001	M	20	II	0	0	0	0	0	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	G1002	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	G1003	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	G1004	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	G1005	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	G1006	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	G1008	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	G1009	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	G1010	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	G1011	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
41	G1012	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	G1013	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	G1014	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	G1015	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	G1016	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	G1017	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	G1018	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	G1019	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	G1020	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	G1021	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
51	G1022	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52	G1023	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
53	G1024	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
54	G1025	M	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
55	G1026	M	28	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
56	G1027	M	52	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
57	G1028	F	42	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
58	G1029	F	50	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
59	G1030	F	50	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
60	G2001	M	20	II	0	0	0	0	**0.5**	0	0	0	0	0	0	0	**1.0**	0	0	0	**0.5**	0	0	0	**1.0**	0	0	0	0	0	0	0	0	0
61	G2002	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
62	G2003	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
63	G2004	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	G2005	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65	G2006	M	29	II	0	0	0	0	**1.0**	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0	0	0	0	0	0	0
66	G2007	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
67	G2008	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
68	G2009	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
69	G2011	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
70	G2012	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	G2013	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
72	G2014	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	G2015	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74	G2016	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	G2017	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
76	G2018	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
77	G2019	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
78	G2020	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
79	G2021	M	21	II	0	0	0	0	0	0	0	**0.5**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80	G2022	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
81	G2023	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
82	G2024	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	**0.5**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
83	G2025	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
84	G2026	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
85	G2027	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
86	G2028	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
87	G2029	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
88	G2030	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
89	G2031	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
90	G2032	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
91	G2033	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
92	G2034	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
93	G2035	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
94	G2036	M	19	II	0	0	0	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
95	G2037	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0
96	G2038	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
97	G2039	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
98	G2040	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
99	G2041	M	41	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	G2042	M	46	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
101	G2043	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
102	G2044	M	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
103	G2045	M	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
104	G2046	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
105	G2047	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
106	G2048	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
107	G2049	M	29	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
108	G2050	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
109	G2051	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
110	G2052	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
111	G2053	M	36	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
112	G2054	M	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
113	G2055	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
114	G2056	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
115	G2057	M	65	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
116	G2058	M	33	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
117	G2059	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
118	G2060	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
119	G2061	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
120	G2062	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
121	G2063	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
122	G2064	M	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
123	G2065	M	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
124	G2066	M	18	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
125	G2067	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
126	G2068	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
127	G2069	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
128	G2070	M	34	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
129	G2071	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
130	G2072	M	26	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
131	G2073	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
132	G2074	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
133	G2075	M	51	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
134	G2076	F	44	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
135	G2077	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
136	G2078	F	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
137	G2079	F	42	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
138	G2080	F	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
139	G2081	F	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
140	G2082	F	41	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
141	G2083	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
142	G2084	F	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
143	G2085	F	54	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
144	G2086	F	26	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
145	G2087	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
146	G2088	F	39	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
147	G2089	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
148	G2090	F	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
149	G2091	F	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
150	G2092	F	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
151	G2093	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
152	G2094	F	32	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
153	G2095	F	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
154	G2097	F	42	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
155	G2098	F	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
156	G2099	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
157	G2100	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
158	G2101	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
159	G2102	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
160	G2103	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
161	G2104	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
162	G2105	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
163	G2106	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
164	G2107	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
165	G2108	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
166	G2109	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
167	G2110	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
168	G2111	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
169	G2112	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
170	G2113	F	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
171	G2114	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
172	G2115	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
173	G2116	F	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
174	G2117	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
175	G2118	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
176	G2119	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
177	G2120	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
178	G2121	F	29	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
179	G2122	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
180	G2123	F	47	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
181	G2124	F	28	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
182	G2125	F	55	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
183	G2126	F	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
184	G2127	M	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
185	G2128	M	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
186	G2129	M	30	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
187	G2130	M	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
188	G2131	M	54	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
189	G2132	M	20	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
190	G2133	M	53	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
191	G2134	M	30	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
192	G2135	M	25	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
193	G2136	M	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
194	G2137	M	20	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
195	G2138	M	27	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
196	G2139	F	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
197	G2140	F	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
198	G2141	F	28	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
199	G2142	F	54	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
200	G2143	F	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
201	G2144	F	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
202	G2145	F	22	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
203	G2146	F	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
204	G2147	F	23	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
205	G2148	F	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
206	G2149	F	23	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
207	G2150	F	51	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mean			29.12																													
SD			11.46																													

Discontinued Subjects (Inner surface)

Table 6b: Basic and supplement score of cutaneous reactions that occurred during the induction and challenge phase of discontinued subjects (two subjects due to skin irritation reaction and one subject due to poor compliance). These subjects were not included in the statistical evaluation.

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	G1007	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Discontinued (Poor compliance)															
2	G2010	M	20	II	0	0	0	0	0	0	**2.0**	0	**2.0**	0	Discontinued (Irritation)												0	0	**0.5**	0	0	0	0	0
3	G2096	F	21	II	0	0	0	0	0	0	0	0	**3.0**	0	**3.0**	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 7a: Modified Draize-95 Test Tabulation of scoring: **Powder Free Nitrile Examination Aloe Vera Gloves - Green** (*Outer surface*) - Basic and Supplemental Score of cutaneous reactions that occurred during the Induction and Challenge Phase (206 subjects).

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	M1	F	43	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	M2	F	50	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	M3	F	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	M4	F	46	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	M5	F	42	III	0	0	0	0	**0.5**	0	**1.0**	0	**0.5**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	M6	F	28	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	M7	F	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	M8	F	22	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	M9	F	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	M10	F	52	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	M11	F	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	M12	F	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	M13	F	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	M14	F	26	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	M15	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	M16	F	49	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0
17	M17	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	M18	F	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	M19	F	44	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	M20	F	35	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	M21	F	41	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	M22	F	42	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0	0	0	0	0	0	0	0	0
23	M23	F	27	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	M24	F	49	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	M25	F	22	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	M26	F	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	M27	F	36	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	M28	F	22	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	M29	F	52	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0
30	M30	M	21	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	G1001	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	G1002	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	G1003	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	G1004	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	G1005	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	G1006	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	G1008	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	G1009	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	G1010	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	G1011	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
41	G1012	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	G1013	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	G1014	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	G1015	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	G1016	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	G1017	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	G1018	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	G1019	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	G1020	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	G1021	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
51	G1022	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52	G1023	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
53	G1024	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
54	G1025	M	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
55	G1026	M	28	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
56	G1027	M	52	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
57	G1028	F	42	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
58	G1029	F	50	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
59	G1030	F	50	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
60	G2001	M	20	II	0	0	0	0	**0.5**	0	0	0	**0.5**	0	0	0	**1.0**	0	0	0	**0.5**	0	0	0	**1.0**	0	0	0	0	0	0	0	0	0
61	G2002	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
62	G2003	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
63	G2004	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	G2005	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65	G2006	M	29	II	0	0	0	0	**1.0**	0	**1.0**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.5**	0	0	0	0	0	0	0	0	0
66	G2007	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
67	G2008	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
68	G2009	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
69	G2011	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
70	G2012	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	G2013	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
72	G2014	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	G2015	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74	G2016	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	G2017	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
76	G2018	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
77	G2019	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
78	G2020	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
79	G2021	M	21	II	0	0	0	0	0	0	0	**0.5**	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80	G2022	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
81	G2023	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
82	G2024	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
83	G2025	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
84	G2026	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
85	G2027	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
86	G2028	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
87	G2029	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
88	G2030	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
89	G2031	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
90	G2032	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
91	G2033	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
92	G2034	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
93	G2036	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
94	G2037	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
95	G2038	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
96	G2039	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
97	G2040	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
98	G2041	M	41	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
99	G2042	M	46	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	G2043	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
101	G2044	M	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
102	G2045	M	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
103	G2046	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
104	G2047	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
105	G2048	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
106	G2049	M	29	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
107	G2050	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
108	G2051	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
109	G2052	M	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
110	G2053	M	36	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
111	G2054	M	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
112	G2055	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
113	G2056	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
114	G2057	M	65	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
115	G2058	M	33	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
116	G2059	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
117	G2060	M	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
118	G2061	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
119	G2062	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
120	G2063	M	35	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
121	G2064	M	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
122	G2065	M	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
123	G2066	M	18	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
124	G2067	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
125	G2068	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
126	G2069	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
127	G2070	M	34	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
128	G2071	M	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
129	G2072	M	26	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
130	G2073	M	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
131	G2074	M	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
132	G2075	M	51	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
133	G2076	F	44	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
134	G2077	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
135	G2078	F	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
136	G2079	F	42	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
137	G2080	F	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
138	G2081	F	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
139	G2082	F	41	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
140	G2083	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
141	G2084	F	30	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
142	G2085	F	54	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
143	G2086	F	26	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
144	G2087	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
145	G2088	F	39	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
146	G2089	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
147	G2090	F	31	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
148	G2091	F	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
149	G2092	F	45	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
150	G2093	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
151	G2094	F	32	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
152	G2095	F	27	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
153	G2097	F	42	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
154	G2098	F	19	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
155	G2099	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
156	G2100	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
157	G2101	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
158	G2102	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
159	G2103	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
160	G2104	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
161	G2105	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
162	G2106	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
163	G2107	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
164	G2108	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
165	G2109	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
166	G2110	F	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
167	G2111	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
168	G2112	F	24	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
169	G2113	F	49	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
170	G2114	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
171	G2115	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
172	G2116	F	22	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
173	G2117	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
174	G2118	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
175	G2119	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
176	G2120	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
177	G2121	F	29	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
178	G2122	F	25	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
179	G2123	F	47	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
180	G2124	F	28	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
181	G2125	F	55	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
182	G2126	F	40	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
183	G2127	M	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
184	G2128	M	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
185	G2129	M	30	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
186	G2130	M	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
187	G2131	M	54	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
188	G2132	M	20	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
189	G2133	M	53	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
190	G2134	M	30	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
191	G2135	M	25	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
192	G2136	M	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
193	G2137	M	20	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
194	G2138	M	27	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
195	G2139	F	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
196	G2140	F	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
197	G2141	F	28	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
198	G2142	F	54	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
199	G2143	F	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
200	G2144	F	29	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
201	G2145	F	22	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
202	G2146	F	24	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
203	G2147	F	23	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
204	G2148	F	26	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
205	G2149	F	23	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
206	G2150	F	51	VI	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mean			29.17																													
SD			11.47																													

Discontinued Subjects (Outer surface)

Table 7b: Basic and supplement score of cutaneous reactions that occurred during the induction and challenge phase of discontinued subjects (three subjects due to skin irritation reaction and one subject due to poor compliance). These subjects were not included in the statistical evaluation.

No	RN	G	Age	ST	Induction Phase																				Challenge Phase							
					Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
					B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	G1007	M	20	II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Discontinued (Poor compliance)															
2	G2010	M	20	II	0	0	0	0	0	0	**2.0**	0	**2.0**	0	Discontinued (Irritation)										0	0	**0.5**	0	0	0	0	0
3	G2035	M	20	II	0	0	0	0	0	0	**2.0**	0	Discontinued (Irritation)												0	0	0	0	0	0	0	0
4	*G2096	F	21	II	0	0	0	0	0	0	0	0	0	0	0	0	Discontinued (Irritation)										0	0	0	0	0	0	0	0

*Subject was discontinued due to skin irritation caused by inner surface of the glove.

Abbreviations:

M	: Male	No	: Number
F	: Female	B	: Basic scores
S	: Supplement scores	G	: Gender
ST	: Skin Type; (According to Fitzpatrick Classification)	RN	: Registration Number
SD	: Standard deviation		

5.5 Interpretation of Results

The study that was completed on non-sensitized adult human subjects, 207 (for inner surface) and 206 (for outer surface) giving all negative results, hence provides more than 95% confidence that the chemical sensitization potential of the tested rubber containing medical device in the user population is expected to be less than 1.5%.

6.0 CONCLUSION

There was no clinical evidence of the presence of residual chemical additives at the level that may induce Type IV allergy in the unsensitized general user population in the tested material, **Powder Free Nitrile Examination Aloe Vera Gloves - Green**.

The skin sensitization test ('Modified Draize-95' Test) of this medical device, **Powder Free Nitrile Examination Aloe Vera Gloves - Green**, tested on 207 non-sensitized human subjects with inner surface and tested on 206 non-sensitized human subjects with outer surface are negative, hence meeting the requirements for the claim: This product demonstrated reduced potential for sensitizing users to chemical additives as described in Guidance for Industry and FDA Staff - Medical Glove Guidance Manual[6].

7.0 REFERENCES

1. "*Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber Products*" on the World Wide Web at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073792.htm#e_2_4
2. ASTM: D6355-07, Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves, Current edition approved Nov. 1, 2007.
3. Robinson MK. Population differences in acute skin irritation responses. Race, sex, age, sensitive skin and repeat subject comparisons. *Contact Dermatitis.* 46(2):86-93, 2002.
4. Foy, V., Weinkauf, R., Whittle, E., Basketter, DA. Ethnic variation in the skin irritation response. *Contact Dermatitis.* 45(6):346-349, 2001.
5. Kompaore F., Tsuruta H. In vivo differences between Asian, black and white in the stratum corneum barrier function. *International Archives of Occupational & Environmental Health.* 65 (1Suppl):S223-5, 1993.
6. "*Medical Glove Guidance Manual*" on the World Wide Web at: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm428191.pdf

8.0 RECORD TO BE MAINTAINED

The study records shall be maintained for a period of two (2) years following the issuance of report.
A copy of this signed report, together with the protocol and all raw data generated at the laboratory are retained in Healthmedic Research archive

9.0 ETHICAL CONSIDERATION

This study is conducted in compliance with the Helsinki Declaration and a written informed consent from the subject is obtained prior to recruitment and filed with the subject's records.
Ethics approval was obtained from:

1) Islamic University of Gaza.
   Ethics approval number: 470/10/IUG
2) Healthmedic Research Ethics Committee (HMREC).
   Ethics approval number: HMREC-HMR-04-2020

10.0 VERIFICATION

Title of study: **'MODIFIED DRAIZE-95' TEST IN NORMAL INDIVIDUAL (HUMAN STUDY)** on Powder Free Nitrile Examination Aloe Vera Gloves – Green

We the undersigned declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.

.....
Dr. Saadiah Sulaiman
Study Director/Principal Investigator

07/08/2020
Date

.....
Dr. Sharifah Ismail
Clinical Investigator

07/08/2020
Date

11.0 QUALITY ASSURANCE INSPECTIONS STATEMENT

Title of study: **'MODIFIED DRAIZE-95' TEST IN NORMAL INDIVIDUAL (HUMAN STUDY)** on Powder Free Nitrile Examination Aloe Vera Gloves – Green

The Quality Assurance Unit selects critical phases of the study for QA inspections prior to experiment starting date. Records of the findings of these inspections are kept in the QA file. The statement below is to confirm that final report reflects the raw data.

This study has been inspected by the Quality Assurance Personnel, and the findings have been reported to the test facility management and to the Study Director on the dates below.

Phases Inspected	Inspected Dates	Dates Reported to Laboratory Director	Dates Reported to Study Director
Procedures	04/02/2020	04/02/2020	04/02/2020
Raw data and records	04/08/2020	04/08/2020	04/08/2020
Draft Report	04/08/2020	04/08/2020	06/08/2020
Final Report	06/08/2020	07/08/2020	07/08/2020

Norfarah Izzaty Razaly
Quality Assurance Personnel

07/08/2020
Date