GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Nahal Islam
Defender Safety
30 Skyline Drive
Plainview, New York 11803

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

Perfect Mask

TEST ARTICLE IDENTIFICATION

DSM-PMW01-P

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Summary

The test article, Perfect Mask, was evaluated for potential cytotoxic effects using an *in vitro* mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 72 hours. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed evidence of causing slight cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Supervisory Personnel: Austin M. Zdawczyk, BS, MBA, ALAT
Manager, Biocompatibility

DocuSigned by:
Signer Name: Collin Tong
Signing Reason: I approve this document
Signing Time: 11-Mar-2021 | 17:10 EST
73A5025A1DD2449295631C3894812FFC

Study Director Approval: _____
Collin P. Tong, BS
Associate Study Director

Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

DocuSigned by:
Collin Tong
Signer Name: Collin Tong
Signing Reason: I approve this document
Signing Time: 11-Mar-2021 | 17:10 EST
73A5025A1DD2449295631C3894812FFC

Study Director: _____
Collin P. Tong, BS

1. Introduction

1.1 Purpose

The purpose of this study was to determine the potential of a test article to cause cytotoxicity.

1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity.

This test was performed in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.

1.3 Dates

Test Article Received:	February 1, 2021
Cells Dosed:	February 26, 2021
Observations Concluded:	February 28, 2021

1.4 GLP Compliance

The study initiated by protocol signature on February 19, 2021 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

2. Identification of Test and Control Articles

The test article provided by the sponsor was identified and handled as described below:

Table 1: Test Article

Name:	Perfect Mask
Identification:	DSM-PMW01-P
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: not applicable because no active ingredients are used to formulate a concentration; Purity: not applicable because the test article does not contain an active ingredient; Composition: Polypropylene, white additives
Physical Description of the Test Article:	Style: Tri-Fold Design Color: White Material: Polypropylene Dimensions: Length: 8.5 cm +/- 1cm Width: 20 cm +/- 2cm
Storage Conditions:	Ambient Temperature

Table 2: Negative Control Article

Name:	High density polyethylene (HDPE)
Stability Testing:	Marketed product, stability characterized by its labeling
Strength, Purity, Composition or Other Characteristics:	Composition: polyethylene

Table 3: Reagent Control Article

Name:	Single strength Minimum Essential Medium supplemented with 5% fetal bovine serum, 2% antibiotics (100 units/mL penicillin, 100 µg/mL streptomycin and 2.5 µg/mL amphotericin B) and 1% (2 mM) L-glutamine (1X MEM)
Stability Testing:	Stable for the duration of the study
Strength, Purity, Composition or Other Characteristics:	Composition: 92% Gibco MEM with Earle's salts, 5% fetal bovine serum, 2% antibiotics (100 units/mL penicillin, 100 µg/mL streptomycin and 2.5 µg/mL amphotericin B), and 1% (2 mM) L-glutamine

Table 4: Positive Control Article

Name:	Powder-Free Latex Gloves
Stability Testing:	Marketed product, stability characterized by its labeling
Strength, Purity, Composition or Other Characteristics:	Composition: natural rubber latex, zinc carbamate accelerators, zinc oxide, and titanium dioxide

Table 5: Extraction Vehicle

Name:	1X MEM

3. Test System

3.1 Test System and Justification of Test System

Mammalian cell culture monolayer consisting of L-929 mouse fibroblast cells free from mycoplasma (ECACC Catalog No. 85103115) was used. *In vitro* mammalian cell culture studies have been used historically to evaluate cytotoxicity of biomaterials and medical devices.

3.2 Test System Management

L-929 mouse fibroblast cells were propagated and maintained in flasks containing 1X MEM at 37°C with 5% carbon dioxide (CO_2). For this study, cells were seeded in 10 cm^2 cell culture wells, labeled with passage number and date, and incubated at 37°C in the presence of 5% CO_2 to obtain subconfluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

4. Method

4.1 Test and Control Article Preparation

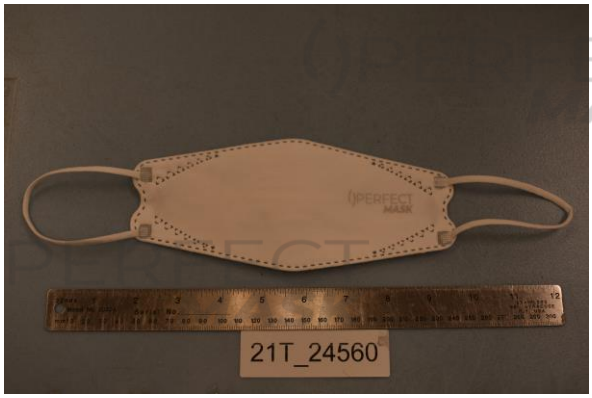
Due to the absorptive nature of the test article, the extraction ratio was based on an absorption capacity. The test article was prepared based on the NAMSA calculated surface area. The test article was not subdivided. A single preparation of the test article and each of the controls were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction. The 1X MEM extraction method was conducted in the presence of serum to optimize extraction of both polar and non-polar components.

Table 6: Extraction

Article	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
Test	60 cm^2:20 mL	647.9 cm^2	216 mL	37°C for 72 hours
Negative Control	3 cm^2:1 mL	31.5 cm^2	10 mL	37°C for 72 hours
Reagent Control	Not Applicable	Not Applicable	10 mL	37°C for 72 hours
Positive Control	6 cm^2:1 mL	60 cm^2	10 mL	37°C for 72 hours

Figure 1: Representative Photograph of the Test Article

Test Article



The following table contains a description of the test and control article extract conditions.

Table 7: Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
1X MEM	Before Extraction	Test Article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Reagent Control	Pink	Clear	None
		Positive Control	Pink	Clear	None
	After Extraction	Test Article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Reagent Control	Pink	Clear	None
		Positive Control	Pink	Clear	None

The test article remained visually unchanged following the extraction process. The extracts were tested immediately following extraction. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

4.2 Test Procedure

Triplicate culture wells were selected which contained a subconfluent cell monolayer. The growth medium contained in the triplicate cultures was replaced with 2.0 mL of the test extract in each well. Similarly, the growth medium in triplicate 10 cm^2 wells was replaced with 2.0 mL of the reagent control, the negative control and the positive control extracts. The wells of each plate were labeled with the appropriate lab number or control and the replicate number. Each plate was labeled with the test code and the dosing date. The wells were incubated at 37°C in 5% CO_2 for 48 hours.

Following incubation, the cells were examined microscopically (100X) to evaluate cellular characteristics and percent lysis.

Table 8: Test Scoring

Grade	Reactivity	Conditions of all Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.
4	Severe	Nearly complete or complete destruction of the cell layers.

The color of the test medium was observed to determine any change in pH. A color shift toward yellow would have indicated an acidic pH range, and a color shift toward magenta to purple would have indicated an alkaline pH range.

For the test to be valid, the reagent control and the negative control must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis. The test article met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated.

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

5. Results

Slight cytotoxicity was noted. No pH shift was observed at 48 hours. The reagent control, negative control and the positive control performed as anticipated. The individual reactivity grades are presented in Appendix 1.

6. Conclusion

The test article extract showed evidence of causing slight cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

7. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

8. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files in accordance with NAMSA SOPs.

9. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity (2009).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems - Requirements for regulatory purposes (2016).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2017).

United States Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro (2020).

Appendix 1 - Reactivity Grades For Elution Testing

Well	Percent Rounding	Percent Cells Without Intracytoplasmic Granules	Percent Lysis	Grade	Reactivity
Test (1)	20	20	20	1	Slight
Test (2)	20	20	20	1	Slight
Test (3)	20	20	20	1	Slight
Negative Control (1)	0	0	0	0	None
Negative Control (2)	0	0	0	0	None
Negative Control (3)	0	0	0	0	None
Reagent Control (1)	0	0	0	0	None
Reagent Control (2)	0	0	0	0	None
Reagent Control (3)	0	0	0	0	None
Positive Control (1)	Not Applicable	Not Applicable	100	4	Severe
Positive Control (2)	Not Applicable	Not Applicable	100	4	Severe
Positive Control (3)	Not Applicable	Not Applicable	100	4	Severe

Note: 1, 2 and 3 denote replicates.

Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis.

Phase Inspected	Date Inspected	Study Director Notification Date	Management Notification Date
Dosing	26 February 2021	26 February 2021	26 February 2021
Final Report Review	11 March 2021	11 March 2021	11 March 2021

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

DocuSigned by:
Jessica Ciesler
Signer Name: Jessica Ciesler
Signing Reason: I have reviewed this document
Signing Time: 11-Mar-2021 | 17:05 EST
7A78F5F4DFF5473AA35D14E9EB701BFD

QA Representative: _____

Jessica Ciesler, MS
Auditor, Quality Assurance

ADD ON

Collin Tong

21T_24560 GLP
50882_001 50882

From: OH Order Processing
Sent: Wednesday, January 27, 2021 12:21 PM
To: Collin Tong
Subject: FW: Electronic Sample Submission 238736-1

Follow Up Flag: Follow up
Flag Status: Completed

21T_24560

From: NAMSA Connect <connect@namsa.com>
Sent: Monday, January 25, 2021 1:41 PM
To: nahal@defendersafety.com
Subject: Electronic Sample Submission 238736-1

Overview

Submission ID: 238736
Revision #: 1
Date Created: 25 Jan 2021
Testing Location: Northwood
Control Article: No
Proposal Number: 1_Q-40345
Quantity Submitted: 15 masks

Billing and Shipping

Bill To: Defender Safety (50882)
30 Skyline Drive
Plainview, New York 11803
United States

Ship To: Defender Safety (50882)
30 Skyline Drive
Plainview, New York 11803
United States

Contact: Nahal Islam (50882_001)
Defender Safety (50882)
nahal@defendersafety.com

Test Article Information

Name: Perfect Mask
Test Article ID: DSM-PMW01-P
Physical Description: Style: Tri-Fold Design Color: White Material: Polypropylene Dimensions: Length: 8.5 cm +/- 1 cm Width: 20 cm +/- 2 cm
Type: Medical Device
Clinical Use: The are used for standard precautions to protect clinicians and patients from pathogens that may spread by blood or other body fluids, secretions or excretions
Sterility: Not Sterile
Can Be Cut: No
Reported Client Specific Number: Perfect Mask Biocompatibility Report/DSM-PMW01-P

Ratio: Surface Area, Material thickness greater or equal to 0.5 mm - ratio of 3 cm^2:mL
Surface Area: ~~170 cm2~~ NAMSA to Calculate
Contains Elastomer: Yes
Storage Conditions: Ambient (15-30 °C)
Shipping Conditions: Ambient
Disposition: Discard used and unused test article

CPT
19FEB21

Special Instructions: Please contact me if there is a discrepancy between our measurement and yours.

GLP Information

Stability: Stability testing is in progress and sponsor affirms that test article is stable for duration of intended testing.
Analysis: Analysis is not necessary due to test article being a solid, powder, gel, or

liquid being extracted or tested as received (mixture with a carrier not needed).

Has Active Ingredient: No

Composition: Polypropylene, white additives.

Testing Services

Test Code	Qty	Proposal	Grouping	STAT	Regulatory Scope	Draft Report	Comments	Purchase Order	Test Spec	Extracts
V0014-130	1	1_Q-40345		No	GLP	No	Please contact me if I have inputted incorrect extraction time for Surgical Mask testing.	PP7166		1x Minimal Essential Media 37°C/72 hours
TI251-800	2	1_Q-40345		No	GLP	No	Please contact me if I have inputted incorrect extraction time for Surgical Mask testing.	PP7166		0.9% Sodium Chloride Solution 50°C/72 hours
TI261-300	2	1_Q-40345		No	GLP	No	Please contact me if I have inputted incorrect extraction time for Surgical Mask testing.	PP7166		0.9% Sodium Chloride Solution 50°C/72 hours
V-ABS-CAP	1	1_Q-40345		No	Medical Device GMP In-Process Testing	No	if needed. Please contact me if I have inputted incorrect extraction time for Surgical Mask testing.	PP7166		~~1x Minimal~~ Essential Media 50°C/72 hours
T-ABS-CAP	2	1_Q-40345		No	~~Medical Device~~ GMP In-Process Testing	No	if needed. Please contact me if I have inputted incorrect extraction time for Surgical Mask testing.	PP7166		0.9% Sodium Chloride Solution 50°C/72 hours

N/A CPT 19FEB21

Authorization

Electronically Signed By: nahal@defendersafety.com **Date:** 25 Jan 2021

Reviewed By (NAMSA Associate Signature): _____ Date: 19FEB21

GLP PROTOCOL

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR

Nahal Islam
Defender Safety
30 Skyline Drive
Plainview, New York 11803

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

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Approvals

Sponsor Representative: Nahal Islam

Date Approved: Feb-11-20201

Study Director (NAMSA): Collin P. Tong

Collin P. Tong, BS
Associate Study Director

Date Initiated: 19FEB21

1. Introduction

1.1 Purpose

The purpose of this study is to evaluate the cytotoxicity of a test article extract using an *in vitro* mammalian cell culture test.

1.2 Testing Guidelines

This study will be conducted based on the requirements of the International Organization for Standardization 10993-5, Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity.

1.3 GLP Compliance

Good Laboratory Practice – This nonclinical laboratory study will be conducted in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58.

2. Identification of Test and Control Articles

2.1 Test Article

The sponsor will submit the test article, Perfect Mask, to be evaluated. The sponsor provided detailed information about the test article to NAMSA on the sample submission form.

2.2 Extraction Vehicle

Single strength Minimum Essential Medium supplemented with 5% fetal bovine serum, 2% antibiotics and 1% L-glutamine (1X MEM)

The extraction conditions shall attempt to exaggerate the clinical use conditions so as to define the potential toxicological hazard; however, they should not in any instance cause physical changes such as fusion or melting, which results in a decrease in the available surface area. A slight adherence of the pieces can be tolerated.

Note: The 1X MEM extraction method is conducted in the presence of serum to optimize extraction of both polar and non-polar components.

2.3 Control Articles

Negative Control: High density polyethylene

Reagent Control: A single aliquot of the extraction vehicle without test article

Positive Control: Powder-free latex gloves

3. Test System

3.1 Test System and Justification

Mammalian cell culture monolayer consisting of L-929 mouse fibroblast cells (ECACC Catalog No. 85103115 or equivalent source) will be used. *In vitro* mammalian cell culture studies have been used historically to evaluate cytotoxicity of biomaterials and medical devices. All stock cultures of cells will be tested to confirm the absence of mycoplasma contamination.

3.2 Test System Management

L-929 mouse fibroblast cells will be propagated and maintained in flasks containing 1X MEM at 37°C with 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells will be seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain subconfluent

monolayers of cells prior to use. Aseptic procedures will be used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

4. Method

4.1 Test Article Preparation

The following information was completed based on the sponsor providing the information to NAMSA. Further instructions may be attached to the protocol.

The sample will be prepared as follows:

The test article will be prepared based on the NAMSA calculated surface area. The test article will not be subdivided

Table 1: Extraction

Vehicle	Extraction Ratio	Extraction Conditions
1X MEM	Ratio 60 cm^2:20 mL*	37°C, 72 hours

* Extraction ratio based on absorption capacity results performed under lab number 21T_24560_02

Note: Only a single test extract will be prepared.

4.2 Control Article Preparation

The negative control will be prepared based on a ratio of 3 cm^2:1 mL extraction vehicle. A single preparation of the material will be extracted using the same conditions as described for the test article.

The reagent control will be prepared using the same conditions as described for the test article.

The positive control will be prepared based on a ratio of 6 cm^2:1 mL of 1X MEM extraction vehicle. A single preparation of the material will be made and extracted at 37°C for 72 (±2) hours.

4.3 Extract Observation

A description of the extract color, clarity and the presence or absence of particulates for the test and control article extracts will be recorded before and after the extraction process, and at the time of dosing. If the extract is stored prior to dosing, storage conditions and time of storage start/stop will be recorded.

4.4 Test Procedure

Each culture well will be selected which contains a subconfluent cell monolayer. The growth medium in triplicate cultures will be replaced with 2 mL of the test extract. Similarly, triplicate cultures will be replaced with 2 mL of the reagent, negative and positive control extracts. Each well will be labeled with the corresponding lab number and the replicate number. Each plate will be labeled with the test code and the dosing date. The wells will be incubated at 37°C in 5% CO_2 for 48 hours.

Following incubation, the cultures will be examined microscopically (100X) to evaluate cellular characteristics and percent lysis.

5. Evaluation and Statistical Analysis

The color of the test medium will be observed. Each culture well will be evaluated for percent lysis and cellular characteristics using the following table:

Table 2: Test Scoring

Grade	Reactivity	Conditions of all Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

For the test to be valid, the reagent control and the negative control must have a reactivity of none (grade 0) and the positive control must be a grade 3 or 4. Percent rounding and percent cells without intracytoplasmic granules are not evaluated in the event of 100% lysis. The test sample meets the requirements of the test if the biological response is less than or equal to grade 2 (mild). The test will be repeated if the controls do not perform as anticipated.

6. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation will be documented and approved by the study director as protocol amendments. Copies will be distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

7. Report

The final report will include information on the cell line, culture medium methods, test and control results, and any additional pertinent observations.

8. Quality Assurance

Inspections will be conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report will also be reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities will be provided with the final report.

9. Records

All raw data pertaining to this study and a copy of the final report will be retained in designated NAMSA archive files in accordance with NAMSA SOPs.

10. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity (2009).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2012).

United States Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro (2020).

Certificate Of Completion

Envelope Id: FF84DE6693924C7B8FB746E00C78FA0F
Status: Completed
Subject: Please DocuSign: 24560-05.doc, 21T_24560 SSF, _05 Protocol.pdf
Source Envelope:
Document Pages: 20
Signatures: 3
Envelope Originator:
Certificate Pages: 2
Initials: 0
Collin Tong
AutoNav: Enabled
ctong@namsa.com
EnvelopeId Stamping: Disabled
IP Address: 12.208.56.162
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Record Tracking

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3/11/2021 5:03:10 PM
Holder: Collin Tong
ctong@namsa.com
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docusignarchive@namsa.com
Location: DocuSign

Signer Events	Signature	Timestamp
Jessica Ciesler jciesler@namsa.com Senior Auditor NAMSA Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 7A78F5F4-DFF5-473A-A35D-14E9EB701BFD Using IP Address: 72.241.205.114 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I have reviewed this document	Sent: 3/11/2021 5:04:21 PM Viewed: 3/11/2021 5:05:04 PM Signed: 3/11/2021 5:05:28 PM

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

Collin Tong ctong@namsa.com Associate Study Director NAMSA Security Level: Email, Account Authentication (Required)	 Signature Adoption: Uploaded Signature Image Signature ID: 73A5025A-1DD2-4492-9563-1C3894812FFC Using IP Address: 12.208.56.162 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 3/11/2021 5:05:29 PM Viewed: 3/11/2021 5:09:48 PM Signed: 3/11/2021 5:10:21 PM

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**
Envelope Summary Events	**Status**	**Timestamps**
Envelope Sent	Hashed/Encrypted	3/11/2021 5:04:21 PM
Certified Delivered	Security Checked	3/11/2021 5:09:48 PM
Signing Complete	Security Checked	3/11/2021 5:10:21 PM
Completed	Security Checked	3/11/2021 5:10:21 PM
Payment Events	**Status**	**Timestamps**