

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Hamid Lamoudan
CTT Group
3000, Avenue Boullé
St-Hyacinthe, Quebec J2S 1H9
Canada

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Direct Contact Method

TEST ARTICLE NAME

CTT-Halo 1

TEST ARTICLE IDENTIFICATION

Antibacterial CADPAT



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Summary

The test article, CTT-Halo 1, was evaluated to determine the potential for cytotoxicity. This study was conducted based on the requirement of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. Culture wells of a 6-well tissue culture plate that contained a subconfluent monolayer of L-929 mouse fibroblast cells were used for testing. Triplicate wells were dosed with either a test article section, high density polyethylene as a negative control, or latex as a positive control. Each article was placed in direct contact with the L-929 cells. After incubating for 24-26 hours, the cultures were examined microscopically (100X) for any abnormal cell morphology and cell lysis in proximity to the articles.

The test article showed evidence of causing mild cell lysis or cytotoxicity to L-929 cells. The test article met the requirements of the test since the grade was equal to a grade 2 (mild reactivity).

Supervisory Personnel: Austin M. Zdawczyk, BS, MBA, ALAT
Senior Manager, Laboratory Services

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.

Study Director Approval:

Signed by:
Jennifer Johnson

 Signer Name: Jennifer Johnson
Signing Reason: I approve this document
Signing Time: 17-Apr-2026 | 13:03 EDT
7E4D71A969E748DFA9B3B151541BAF7B

Jennifer M. Johnson, BS, LAT
Study Director

1. Introduction

1.1 Purpose

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

1.2 Testing Guidelines

This study was conducted based on the ISO 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:	March 26, 2026
Cells Dosed:	April 13, 2026
Observations Concluded:	April 14, 2026

1.4 GLP Compliance

The study initiated by protocol signature on April 7, 2026 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:	CTT-Halo 1
Identification:	Antibacterial CADPAT
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: The fabric is made of 50% nylon and 50% cotton.
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: 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 4: Ancillary Materials

Growth Medium:	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)
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3. Test System

3.1 Test System and Justification

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

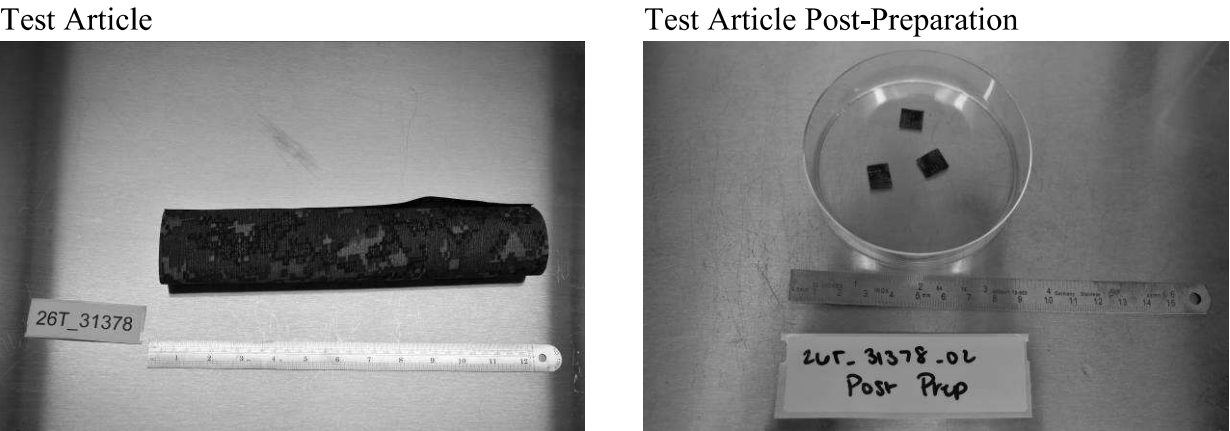
L-929 mouse fibroblast cells were propagated and maintained in flasks containing 1X MEM at 37°C with 5% carbon dioxide (CO₂). For this study, cells were seeded in 10 cm² cell culture wells, labeled with passage number and date, and incubated at 37°C in 5% CO₂ to obtain subconfluent monolayers of cells 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 Article Preparation

Triplicate wells were dosed with the test article having an approximate 1 cm x 1 cm area. The internal side (the side not labeled “face side”) was dosed against the test system.

Figure 1: Representative Photographs of the Test Article



4.2 Control Article Preparation

Negative Control: Triplicate wells were dosed with a 1 cm length portion of HDPE.

Positive Control: Triplicate wells were dosed with a 1 cm x 1 cm portion of latex.

4.3 Test Procedure

The culture wells selected contained a subconfluent cell monolayer. The subconfluency and cell morphology were verified prior to test initiation. The growth medium in each cell culture well was replaced with 0.8 mL of 1X MEM supplemented with 0.001% neutral red. Each prepared test article section was placed on separate cell surfaces in each of triplicate wells. Similarly, the negative control and positive control sections were placed in triplicate wells. Care was taken to prevent unnecessary movement of the specimens. Each plate was incubated at 37°C in 5% CO₂ for 24-26 hours.

Following incubation, the cultures were examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). After macroscopic examination, the cell monolayers were examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles.

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. Evaluation

Scoring for cytotoxicity was based on the following criteria:

Table 5: Test Scoring

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectible zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extending specimen size up to 1.0 cm
4	Severe	Zone extending farther than 1.0 cm beyond specimen

For the suitability of the system to be confirmed, the negative control must have been a grade of 0 (reactivity none) and the positive control must have produced a zone of lysis for a grade equal to or greater than a grade of 3 (reactivity moderate to severe). The test article met the requirements of the test if all three monolayers exposed to the test article showed cytotoxicity no greater than a grade of 2 (reactivity mild).

6. Results

The scores obtained were as follows:

Table 6: Test Scores

Test/Control Articles	Zone of Lysis (mm)	Lysis Under Article	Grade	Reactivity
Test Article: (1)	0	Complete	2	Mild
(2)	0	Complete	2	Mild
(3)	0	Complete	2	Mild
Negative Control: (1)	0	None	0	None
(2)	0	None	0	None
(3)	0	None	0	None
Positive Control: (1)	10	Complete	3	Moderate
(2)	21	Complete	4	Severe
(3)	15	Complete	4	Severe

Note: (1), (2), and (3) denote replicates.

7. Conclusion

The test article showed evidence of causing mild cell lysis or cytotoxicity to L-929 cells. The test article met the requirements of the test since the grade was equal to 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.

8. 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.

9. 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.

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 (2021).

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-National Formulary (USP-NF), General Chapter <87>, Biological Reactivity Tests, *In Vitro* (01 AUG 2016).

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Study Director Notification Date	Management Notification Date
Scoring	April 14, 2026	April 14, 2026	April 14, 2026
Final Report Review	April 17, 2026	April 17, 2026	April 17, 2026

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).

Signed by:





Signer Name: Luis Garcia-Cruz

Signing Reason: I have reviewed this document

Signing Time: 17-Apr-2026 | 11:36 EDT

72BE0CF5AAD9485DAF5639BDB5490C8B

QA Representative:

Luis Garcia-Cruz

Senior Auditor, Quality Assurance

Taylor Irwin

From: OH Order Processing
Sent: Thursday, March 26, 2026 3:53 PM
To: Jenny Johnson
Cc: Taylor Irwin
Subject: FW: Electronic Sample Submission 488552-1

Categories: JMH

26T_31378

From: connect@namsa.com <connect@namsa.com>
Sent: Wednesday, March 25, 2026 12:10 PM
To: hlamoudan@gcttg.com
Subject: Electronic Sample Submission 488552-1

Overview

Submission ID: 488552
Revision #: 1
Date Created: 25 Mar 2026
Testing Location: Northwood
Control Article: No
Proposal Number: 1_Q-124259
Quantity Submitted: 1

Billing and Shipping

Bill To: CTT Group (50072)
 3000, Avenue Boullé
 St-Hyacinthe, Quebec J2S 1H9
 Canada
Ship To: CTT Group (50072)
 3000, Avenue Boullé
 St-Hyacinthe, Quebec J2S 1H9
 Canada
Contact: Hamid Lamoudan (50072_008)
 CTT Group (50072)
 hlamoudan@gcttg.com
 450-501-4959

Test Article Information

Name: CTT-Halo 1
Test Article ID: Antibacterial CADPAT
Physical Description: Fabric treated with an antibacterial treatment
Type: Other
Type Other: Treated textile
Clinical Use: The treated fabric is intended for use in military applications as a functional antimicrobial textile for personnel equipment and field use
Sterility: Aseptically Prepared
Can Be Cut: Yes
Is An Absorbent: No
Reported Client Specific Number:
Special Instructions:

Contains Elastomer: No
Storage Conditions: Ambient (15-30 °C)
Shipping Conditions: Ambient
Shipping Receipt Date: Already Shipped
Disposition: Discard used and unused test article

GLP Information

Stability: Stability testing is in progress and sponsor affirms that test article is stable for duration of intended testing.

Analysis is not necessary due to test article being a solid, powder, gel, or
Analysis: liquid being extracted or tested as received (mixture with a carrier not needed).

26T-31378

Has Active Ingredient: No

Composition: The fabric is made of 50% nylon and 50% cotton.

Fabrication Method Documented: Yes

Testing Services

Test Code	Qty	Proposal	Grouping	STAT	Regulatory Scope	Draft Report	Comments	Purchase Order	Test Spec	Extracts
V0705-001	1	1_Q-124259		No	GLP	No	The sample I submitted is treated CADPAT fabric. I have specified the face side in the textile.	T26-0243 HL		
TI262-809	1	1_Q-124259		No	GLP	No	The sample I submitted is treated CADPAT fabric. I have specified the face side in the textile.	T26-0243 HL		

Attachments

File Name	Comment
T26-0243 HL-NAMSA.pdf	P.O

Authorization

Electronically Signed By: hlamoudan@gcttg.com

Date: 25 Mar 2026

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

Due to the current volume of chemical characterization and GLP biocompatibility testing, NAMSA has made process improvements to better serve you. Sponsors will not receive an assigned GLP study director until test articles arrive at the NAMSA laboratory. Following test article arrival, a study director will be assigned to begin work on study protocols. By making this process improvement, we can reduce the time required to initiate testing in our NAMSA laboratories. This does not apply to pre-clinical/surgical studies and does not modify any process in place for Non GLP studies. Thank you.

GLP PROTOCOL

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR

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St-Hyacinthe, Quebec J2S 1H9
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STUDY TITLE

Cytotoxicity Study Using the ISO Direct Contact Method



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Approvals

Sponsor Representative:

Signé par :
Hamid Lamoudan
Nom du signataire : Hamid Lamoudan
Motif de la signature : J'approuve ce document
Heure de signature : 07-avr.-2026 | 09:08 EDT
EC4A188154CB4468832D5CE69D78D4E4

Study Director (NAMSA):

Signed by:
Jennifer Johnson
Signer Name: Jennifer Johnson
Signing Reason: I approve this document
Signing Time: 07-Apr-2026 | 09:35 EDT
7E4D71A969E748DFA9B3B151541BAF7B

Jennifer M. Johnson, BS, LAT
Study Director

1. Introduction

1.1 Purpose

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

1.2 Testing Guidelines

This study will be conducted based on the requirements of the ISO 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, CTT-Halo 1, to be evaluated. The sponsor provided detailed information about the test article to NAMSA on the sample submission form.

2.2 Control Articles

Negative Control: High density polyethylene (approximate 1 cm length)

Positive Control: Powder-free latex gloves (approximate 1 cm x 1 cm section)

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 single strength Minimum Essential Medium supplemented with 5% fetal bovine serum, 1% Penicillin-streptomycin, 1% Amphotericin B and 1% L-glutamine (1X MEM) at 37°C with 5% carbon dioxide (CO₂). For this study, cells will be seeded in 10 cm² cell culture wells, labeled with passage number and date, and incubated at 37°C in 5% CO₂ 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 cut into a section having an approximate 1 cm x 1 cm area surface area. The internal side (side not labeled face side) will be applied against the test system.

4.2 Test Procedure

The culture wells selected will contain a subconfluent cell monolayer. The growth medium in each cell culture well will be replaced with 0.8 mL of 1X MEM supplemented with 0.001% neutral red.

An appropriately prepared test article section (see Preparation of Test Article) will be placed in three separate cell culture wells. Similarly the negative control and the positive control sections will each be placed in three separate cell culture wells. Care will be taken to prevent unnecessary movement of the specimens. The wells will be labeled with the corresponding lab number and dosing date and incubated at 37°C in 5% CO₂ for 24-26 hours.

Following incubation, the cultures will be examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). After macroscopic examination, the cell monolayers will be examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles.

5. Evaluation

Scoring for cytotoxicity will be based on the following criteria:

Table 1: Test Scoring

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectible zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extending specimen size up to 1.0 cm
4	Severe	Zone extending farther than 1.0 cm beyond specimen

For the suitability of the system to be confirmed the negative control must have a grade of 0 (reactivity none), and the positive control must have produced a zone of lysis (reactivity moderate to severe). The test article meets the requirements of the test if all three monolayers exposed to the test article show no greater than a grade of 2 (reactivity mild). Repeat the test 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 the test and control preparation, information on the cell line, the methods, the score for the test article and controls and any additional pertinent information.

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 (2021).

United States Pharmacopeia-National Formulary (USP-NF), General Chapter <87>, Biological Reactivity Tests, *In Vitro* (01 AUG 2016).



Certificate Of Completion

Envelope Id: AA07F19F-1E69-43E7-B927-69DF3FB4ACE8

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Document Pages: 15

Signatures: 4

Envelope Originator:

Certificate Pages: 4

Initials: 0

Taylor Irwin

AutoNav: Enabled

tirwin@namsa.com

Envelopeld Stamping: Enabled

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Status: Original

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4/7/2026 9:36:26 AM

docusignarchive@namsa.com

Signer Events	Signature	Timestamp
Hamid Lamoudan		Sent: 4/6/2026 9:55:30 AM
hlamoudan@gcttg.com		Viewed: 4/7/2026 8:03:19 AM
Security Level: Email, Account Authentication (Required), Logged in		Signed: 4/7/2026 9:16:55 AM
	Signature Adoption: Pre-selected Style	
	Signature ID:	
	EC4A1881-54CB-4468-832D-5CE69D78D4E4	
	Using IP Address: 24.226.183.180	
	With Signing Authentication	
	(See Authentication Details)	
	With Signing Reasons (on each tab):	
	J'approuve ce document	
	J'approuve ce document	

Authentication Details

Identity Verification Details:

Workflow ID: c368e411-1592-4001-a3df-dca94ac539ae

Workflow Name: Phone Authentication

Workflow Description: Recipient will need to authenticate with their phone number via SMS or a phone call

Transaction Unique ID: 3ed7cf5c-cd2f-5732-a29a-36000b4901ff

Result: Phone Verification Passed

Selected Method: SMS

Phone Number: +1 873-559-1096

Performed: 4/7/2026 8:03:10 AM

Identity Verification Details:

Workflow ID: c368e411-1592-4001-a3df-dca94ac539ae

Workflow Name: Phone Authentication

Workflow Description: Recipient will need to authenticate with their phone number via SMS or a phone call

Transaction Unique ID: 3ed7cf5c-cd2f-5732-a29a-36000b4901ff

Result: Phone Verification Passed

Selected Method: SMS

Phone Number: +1 873-559-1096

Performed: 4/7/2026 9:07:47 AM

Electronic Record and Signature Disclosure:

Accepted: 4/7/2026 8:03:19 AM

ID: 2b686f89-a0b1-40a4-9e41-322ed690bd83

Signer Events	Signature	Timestamp
Jennifer Johnson jmjohnson@namsa.com Study Director North America Science Associates, LLC. Security Level: Email, Account Authentication (Required), Logged in	Jennifer Johnson Signature Adoption: Pre-selected Style Signature ID: 7E4D71A9-69E7-48DF-A9B3-B151541BAF7B Using IP Address: 65.27.36.19 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document I approve this document	Sent: 4/7/2026 9:16:57 AM Viewed: 4/7/2026 9:35:37 AM Signed: 4/7/2026 9:36:22 AM
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
Taylor Irwin tirwin@namsa.com Admin Assistant NAMSA Security Level: Email, Account Authentication (Required)	COPIED	Sent: 4/7/2026 9:36:26 AM Viewed: 4/7/2026 9:36:26 AM Signed: 4/7/2026 9:36:26 AM
Electronic Record and Signature Disclosure: Not Offered via Docusign		

Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	4/6/2026 9:55:31 AM
Certified Delivered	Security Checked	4/7/2026 9:35:37 AM
Signing Complete	Security Checked	4/7/2026 9:36:22 AM
Completed	Security Checked	4/7/2026 9:36:22 AM
Payment Events	Status	Timestamps
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