

LUCA **V-Defense** Nasal Spray

Prevention of respiratory viral infections

LUCA AICell, Inc.

Bio-Platform Company

based on the Artificial Intelligence of Ultimate Nanotechnology











The global trend to lift outdoor mask mandate

While most OECD member countries have lifted the obligation to wear indoor and outdoor masks and declared daily recovery, in the case of Korea, as of January 2023, the outdoor and indoor mask mandatory has been lifted.

【 The status of mandatory indoor/outdoor masks in OECD countries 】

January 2023

Country	 United States	 United Kingdom	 Germany	 France	 Singapore	 New Zealand	 Japan	 South Korea
Outdoor	X	X	X	X	X	X	X	X
Indoor	X	X	X	X	X	X	X	X
Mask mandatory facility			Medical facility, Long-distance train		Medical facility and sanatorium, Public transportation	Medical facility and sanatorium		Medical facility, Public transportation

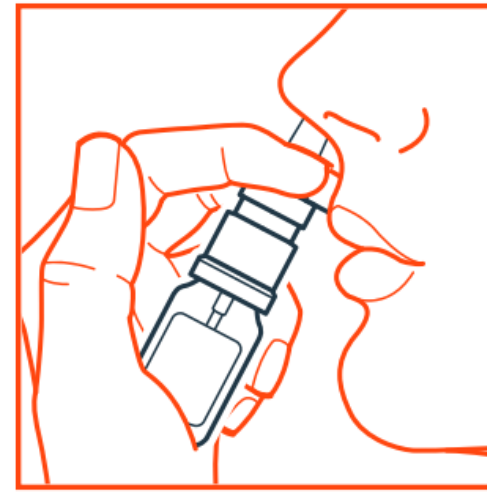
Safety devices to replace masks are required

The risk of respiratory viral infection remains as the COVID-19 mutant virus continues to emerge, and seasonal flu is also prevalent periodically.

The LUCA V-Defense Nasal Spray is
a minimal safety device that can prevent respiratory viral infections
such as COVID-19 and influenza, replacing the mask used for a long time.

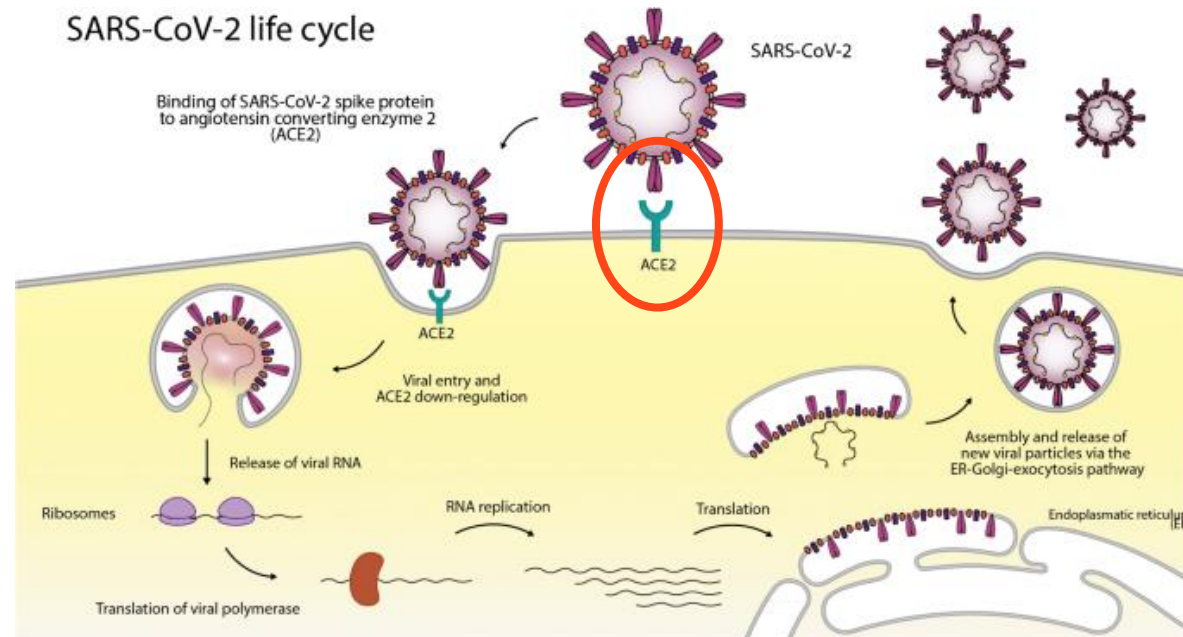


Lift
outdoor
mask
mandate



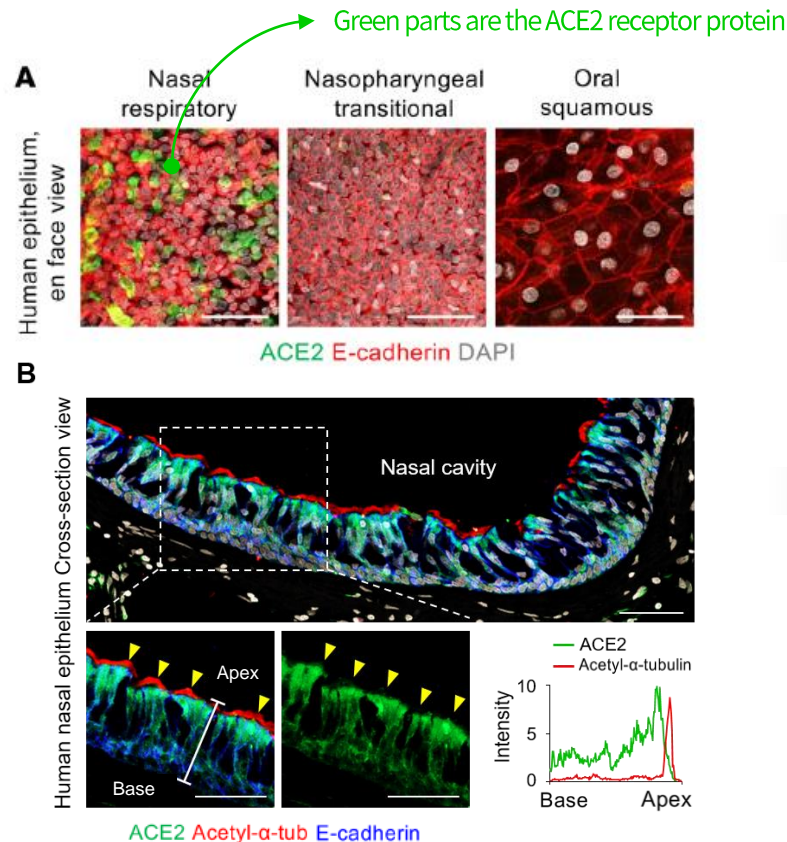
COVID-19 Virus Infection Route(1/3)

COVID-19 virus penetrates cells through **ACE2 receptors** and causes infection.



COVID-19 Virus Infection Route(2/3)

Large amounts of **ACE2 receptors** exist only in the nasal respiratory epithelium, and the nasal respiratory epithelium is the first route for the COVID-19 virus to penetrate the human body.



The human upper respiratory tract is composed of nasal respiratory epithelium, nasopharynx transitional epithelium, and oral squamous epithelium. **It has been found that large amounts of ACE2, the receptor for the COVID-19 virus exist only on the surface of the nasal respiratory epithelium.**

ACE2 receptors are concentrated at the top end of the nasal respiratory epithelium in contact with air.

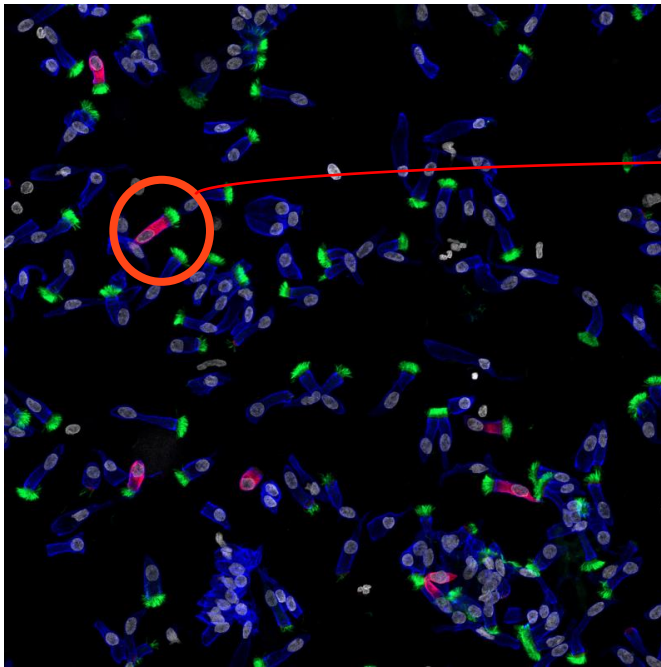
The nasal respiratory epithelium is the first path where the COVID-19 virus penetrates the human body. Blocking this penetration path is very important in preventing infection.

* Source : Nasal Ciliated Cells are Primary Targets for SARS-CoV-2 Replication in Early Stage of COVID-19, Journal of Clinical Investigation (2021)

COVID-19 Virus Infection Route(3/3)

As a result of visual analysis through immunofluorescence staining, it was confirmed that the COVID-19 virus first replicated/proliferated through **nasal ciliated cells**.

[Reference] Tracking the first infection route of the COVID-19 virus through cell smear immunofluorescence staining



Among nasal cells, only ciliated cells (Green) have been found to replicate/proliferate the COVID-19 virus (Red)

- Blue: Nasal epithelial cells
- Green: Nasal ciliated cells
- Red: COVID-19 virus

* Source : Nasal Ciliated Cells are Primary Targets for SARS-CoV-2 Replication in Early Stage of COVID-19, Journal of Clinical Investigation (2021)

Product Specification

It physically coats the nasal mucosa to prevent respiratory viral infections such as COVID-19, the flu, and the common cold.

Intended purpose

- To protect the nasal mucous membrane from infection by the respiratory viruses via formation of a physical membrane when spraying this product to the nose.

Principles of operation

- This product contains an unscented, colourless, a transparent viscous lipid and lambda carrageenan provided in nasal spray devices which consist of high-density polyethylene containers, caps, nozzles, and safety clips. When sprayed to the nose, this product forms a **physical film in the nasal mucosa to prevent respiratory tract infections by viruses.**

The main ingredients

- Lambda Carrageenan, SPAN20, Sodium Hydroxide, Eucalyptol, L-menthol, D-Sorbitol Solution 70%, Benzoic Acid, Benzyl Alcohol, Purified Water

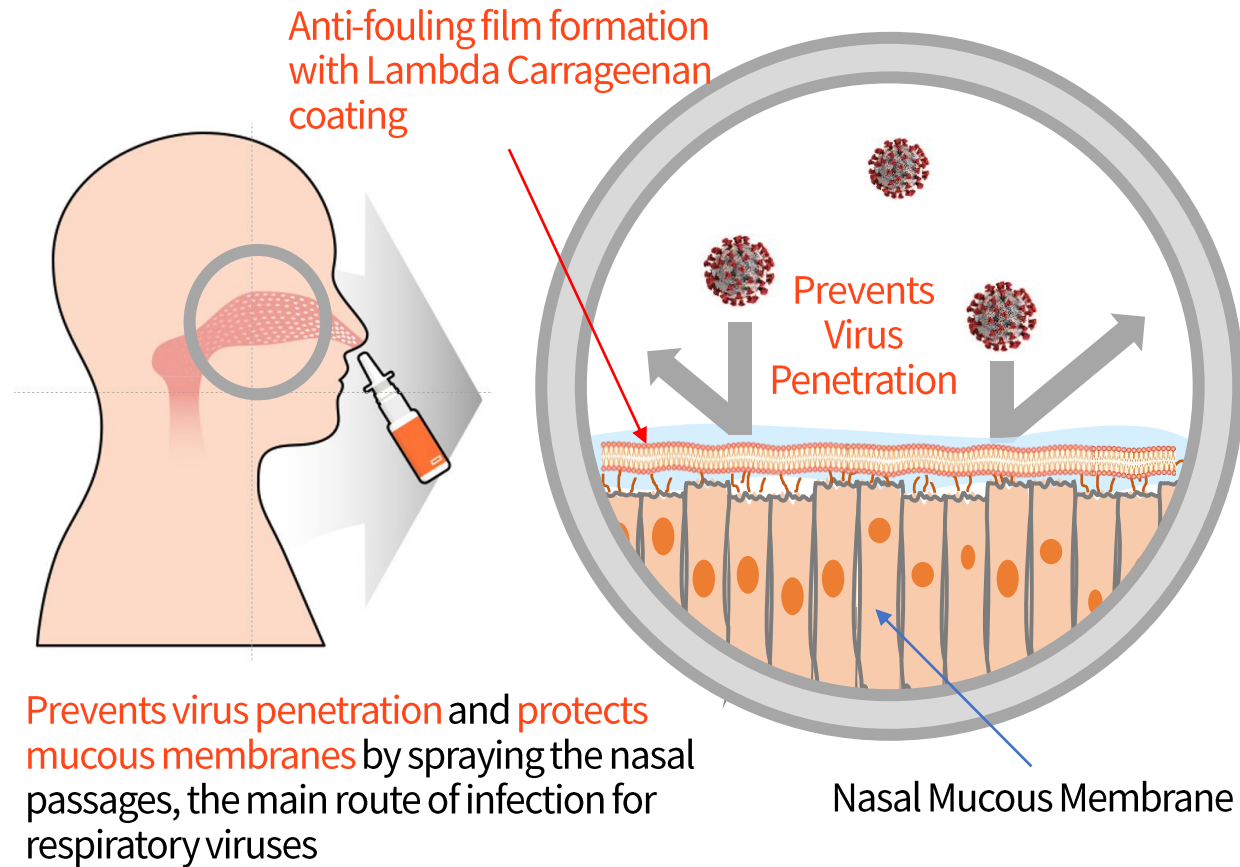
Capacity of Product

- 20ml (About 200 times and 1 month usage)



Prevention of respiratory viral infections

It physically coats the nasal mucosa to prevent respiratory viral infections such as COVID-19, the flu, and the common cold.



Use Case

It is recommended for use in various environments requiring the protection of the nasal mucosa.



Before and after
visiting concert halls
and playgrounds



Days with a lot of
fine dust and pollen



Before visiting a place
where you can
communicate with
many people, such as
school or company



When riding the subway,
bus or plane
(Can be brought on board)



When concerned about
respiratory viruses
(COVID-19, flu, etc.)



How to Use

Usage instructions and steps for using a pump bottle

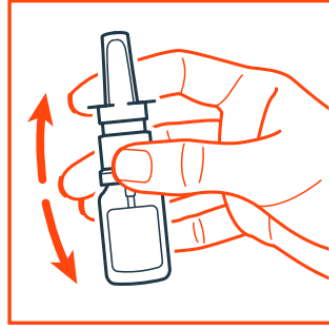
Spray the product three times a day through each nostril to prevent respiratory virus infections of nasal epithelium. If there are any signs or symptoms of virus infection, spray the product several times a day and/or each time through each nostril.

01



Clean inside of your nose

02



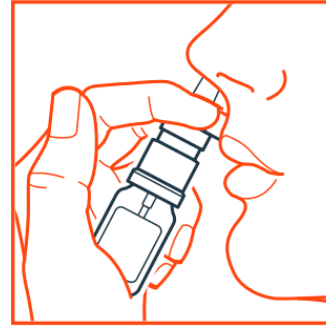
Shake the product gently and open the safety clip and cap.

03



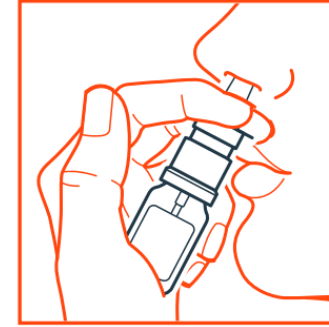
For first-time application, pump 2-3 times in the air.

04



Hold the container upright and insert the nozzle into the nose.

05



Hold your breath for a moment, spray 1 time into each nostril and inhale lightly.

06



After use, clean the nozzle and close the safety clip and cap.

Antiviral performance study result

99.7%

Mahidol University, a Thai professional testing and certification agency, confirmed 99.7% sterilization performance within **a minute** as a result of an **antiviral study using viruses causing COVID-19.**

According to detection method namely virus inhibition assay and 50% tissue culture infectious dose assay (TCID50), we found that **“LUCA V-Defense Nasal Spray”** with concentrated solution can reduce the amount of Severe Acute Respiratory Syndrome **Coronavirus 2 (SARS-CoV-2)** at 99.70% with the minimal contact time of 1 minute.

MAHIDOL UNIVERSITY

No. TM78.115/00365

14 February 2022

ML (THAILAND) CO., LTD
283/18, Unit No. 105-2, 10th Floor, Home place, Soi Sukhumvit 55
Sai Subanvit 55 (Thonglor 13), Klongton Nua, Wattana Bangkok 10110 Thailand

Dear ML (THAILAND) CO., LTD,

According to detection method namely virus inhibition assay and 50% tissue culture infectious dose assay (TCID50), we found that “LUCA V-Defense Nasal Spray” with concentrated solution can reduce the amount of Severe Acute Respiratory Syndrome **Coronavirus 2 (SARS-CoV-2)** at 99.70% with the minimal contact time of 1 minute.

Sincerely yours,

P. S. Sanguan
Pamawan Laksungkrong (PhD)
Associate Professor,
Head, Department of Microbiology and Immunology,
Head, Tropical Medicine Diagnostic Reference Laboratory

Department of Microbiology and Immunology, Faculty of Tropical Medicine, Mahidol University
4200, Nakhon Si Thammaraj Road, Bangkok 10400 Thailand Tel: 002-2260-0112-3-2260-0104-4 Fax: 002-2260-0103

MAHIDOL UNIVERSITY

TEST REPORT

Company Name ML (THAILAND) CO., LTD
Address 283/18, Unit No. 105-2, 10th Floor, Home place, Soi Sukhumvit 55 (Thonglor 13), Klongton Nua, Wattana Bangkok 10110 Thailand

TEST PRODUCT INFORMATION

Received Date 17 December 2021 Testing Date 02 February 2022
Reported Date 14 February 2022 Sample No. B-395-02

Product Name LUCA V-Defense Nasal Spray

Product Characteristics
Packaging Nasal spray
Spray bottle

Active ingredient
1. Sodium monochlorate
2. Lambda Cargenasein
3. Sodium Hydroxide
4. Eucalyptol
5. Liniment

Supplier LUCA AICELL INC.
Distributor ML (THAILAND) CO., LTD
Reg. No. - Lot No. -
Mfg. Date - Exp. Date -

Size of sample 20 ml No. of Samples 1 bottle

TEST METHOD

Test Method Virus Inhibition Assay and 50% Tissue Culture Infectious Dose Assay (TCID50)

Reference Standard ASTM E1655-20: Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Responsive Environmental Surfaces

Test Organisms Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Human isolated)
Titer = 1×10^6 TCID50/ml

Department of Microbiology and Immunology, Faculty of Tropical Medicine, Mahidol University
4200, Nakhon Si Thammaraj Road, Bangkok 10400 Thailand Tel: 002-2260-0112-3-2260-0104-4 Fax: 002-2260-0103

MAHIDOL UNIVERSITY

RESULTS

The purpose of this study was to determine the virucidal efficacy of “LUCA V-Defense Nasal Spray” against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Human isolated). At the concentrated solution with a contact time of 1 minute, the tested product has the efficacy as shown in the table.

Product	Testing concentration	Contact time	Result
			Efficacy (%) Log Reduction
LUCA V-Defense Nasal Spray	Conc.	1 minute	99.70% 2.520

P. S. Sanguan
Assistant Professor (Associate Professor)
Scholar
14 February 2022

P. S. Sanguan
Associate Professor (Associate Professor)
Technical Manager
14 February 2022

Test report only applies to the product mentioned in the test report.
Test report may not be duplicated or used in part without prior written permission.
Test report does not authorize to use as advertising materials.

Department of Microbiology and Immunology, Faculty of Tropical Medicine, Mahidol University
4200, Nakhon Si Thammaraj Road, Bangkok 10400 Thailand Tel: 002-2260-0112-3-2260-0104-4 Fax: 002-2260-0103

Product	Testing concentration	Contact time	Result	
			Efficacy (%)	Log Reduction
LUCA V-Defense Nasal Spray	Conc.	1 minute	99.70%	2.520

Papers related to efficacy (1/4)

As a result of testing the carrageenan coating ability, it was confirmed that the multi-layer composition was perfectly coated on the surface and protected by forming a nano-sized physical film.

K-carrageenan/chitosan nanolayered coating for controlled release of a model bioactive compound

Innovative Food Science and Emerging Technologies 16 (2012) 227–232

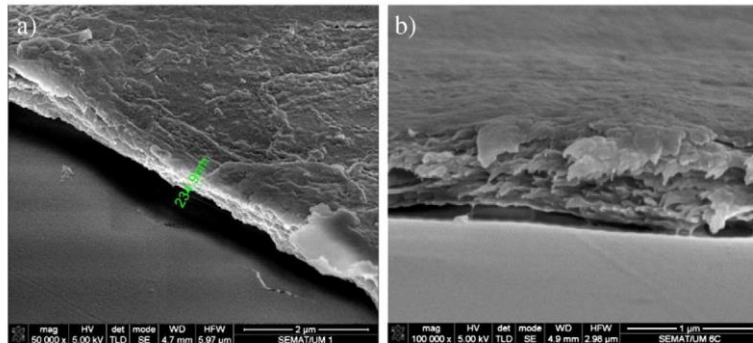
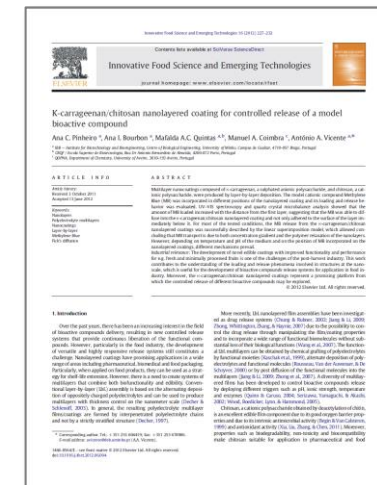


Fig. 4. SEM images of the κ -carrageenan/chitosan coating with MB in the 6th layer. Thickness of the layers (a). Detail of the structure of the layers (b).

- Carrageenan and chitosan nanolayers were demonstrated using equipment capable of measuring nanoscale, such as SEM images.
- The SEM image of the coating with MB in the 6th layer was shown as an example.
- The total thickness of the carrageenan/chitosan layers was 234.9 nm (Fig.4 a).

ELSEVIER



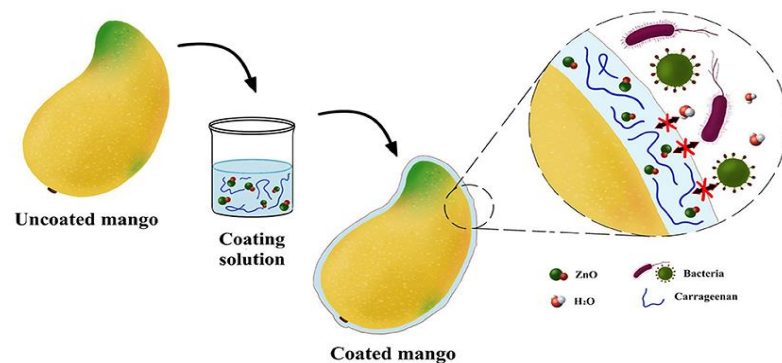
- Related paper
<https://repositorium.sdum.uminho.pt/bitstream/1822/23356/1/1-s2.0-S1466856412000902-main.pdf>

Papers related to efficacy (2/4)

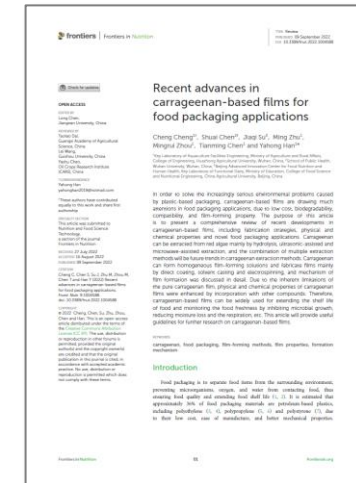
As a result of the carrageenan film formation experiment, **excellent coating ability** and **film retention ability** were confirmed.

Recent advances in carrageenan-based films for food packaging applications

Frontiers in Nutrition, 10.3389/09 Sep. 2022



- The film-forming function of carrageenan and its principle were explained, and its application was demonstrated.
- As one of the methods, carrageenan was coated on fruit (mango), and the coated fruit was fresher for 14 days than the uncoated fruit.
- Because the addition of zinc oxide nanoparticles allowed the composite coating to significantly increase the tensile strength by 43%, reduce the water vapor transmission by 9%, and inhibit the growth of *E. coli*, compared with that of pure carrageenan coatings.



- Related paper
<https://pubmed.ncbi.nlm.nih.gov/36159449/>

Papers related to efficacy (3/4)

It has been confirmed that carrageenan is a safe ingredient that is **not absorbed into the human body** because it has a large molecular weight and **cannot be absorbed into the nasal mucosa or skin**.

Non-Clinical Safety Evaluation of Intranasal Iota-Carrageenan

PLOS ONE | DOI:10.1371/journal.pone.0122911, April 13, 2015

Table 1. Comparison of P_{app} Values for Indicated Test Compounds across Bovine Nasal Mucosa.

	pH 7.5 P_{app} [$\times 10^{-6}$ cm/s]	pH 5.5 P_{app} [$\times 10^{-6}$ cm/s]
Sodium Fluorescein	11.17 \pm 1.02	5.20 \pm 2.12
FD10	0.51 \pm 0.51	0.30 \pm 0.09
FD40	0.18 \pm 0.13	0.31 \pm 0.24
FD70	0.07 \pm 0.06	0.17 \pm 0.10
MANT	17.62 \pm 1.19	11.41 \pm 4.59
MANT-iota-carrageenan	< 0.01	< 0.01

Data are means \pm SD of 3 (MANT) or 5 (all other compounds) experiments.
 P_{app} = apparent permeability coefficient.

doi:10.1371/journal.pone.0122911.t001

- It was confirmed that carrageenan was not absorbed into Bovine Nasal Mucosa by mixing MANT dye with carrageenan.
- MANT dye is a substance absorbed by Bovine Nasal Mucosa, but it was measured that it was not absorbed by Bovine Nasal Mucosa when mixed with carrageenan.
- A pH of 7.5 indicates normal bovine nasal mucosa and a pH of 5.5 indicates inflamed bovine nasal mucosa.



- Related paper
<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0122911>

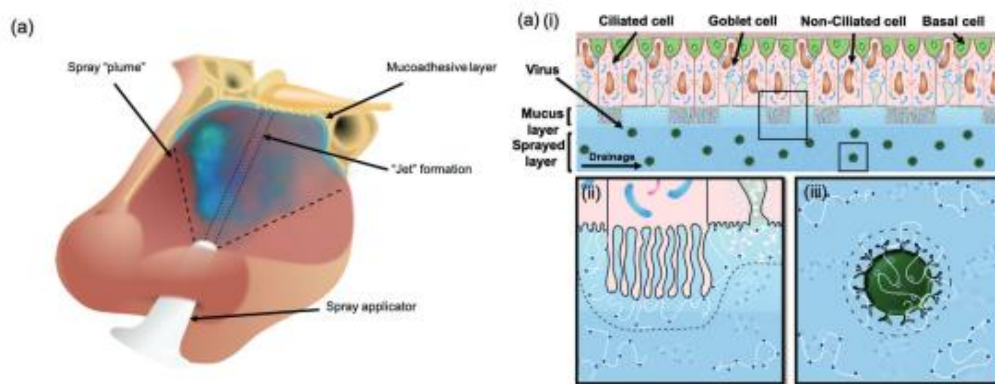
Papers related to efficacy (4/4)

Nasal sprays have been shown to be a very effective way to block the transmission of the virus to humans.

Formulation of a Composite Nasal Spray Enabling Enhanced Surface Coverage and Prophylaxis of SARS-CoV-2

July 2021 *Advanced Materials* 33(26):2008304

- On application, nasal sprays directly contact the nasal mucosa lining the epithelium.
- Demonstration of potential removal of the virus via trapping within the sprayed layer and elimination through natural nasal clearance mechanisms (sneezing/nose-blowing/swallowing).
- Demonstration of potential blocking of virus uptake into the cells as the polymer creates a steric barrier across the cell interface.
- And demonstration of potential inhibition of virus uptake by creating a steric barrier around the interface of the virus.



- Related paper
https://www.researchgate.net/publication/352025483_Formulation_of_a_Composite_Nasal_Spray_Enabling_Enhanced_Surface_Coverage_and_Prophylaxis_of_SARS-CoV-2

| Menthol Scent

LUCA V-Defense Nasal Spray contains **everyone's favorite menthol scent**, you can use it comfortably.



Pre-Clinical Report

The safety test results have been confirmed to be safe as if it is harmless to the human body by the authentication institution.

【Cytotoxicity Test】

The image shows two pages of a Cytotoxicity Test report from KTC. The top page is the cover sheet (Cover Sheet) and the bottom page is the test results page (Test Results). The cover sheet includes the title 'Pre-Clinical Report', the test name 'Cytotoxicity Test', and the test results 'No adverse reactions observed'. The test results page includes a table with columns for 'Test Item', 'Test Method', 'Test Result', and 'Test Date'. The test results are summarized as 'No adverse reactions observed'.

It does not cause cytotoxicity reactions

【Intracutaneous Reactivity Test】

The image shows two pages of an Intracutaneous Reactivity Test report from KTC. The top page is the cover sheet (Cover Sheet) and the bottom page is the test results page (Test Results). The cover sheet includes the title 'Pre-Clinical Report', the test name 'Intracutaneous Reactivity Test', and the test results 'No adverse reactions observed'. The test results page includes a table with columns for 'Test Item', 'Test Method', 'Test Result', and 'Test Date'. The test results are summarized as 'No adverse reactions observed'.

There are no adverse reactions as a result of the intracutaneous reactivity test

【Skin Sensitization Test】

The image shows two pages of a Skin Sensitization Test report from KTC. The top page is the cover sheet (Cover Sheet) and the bottom page is the test results page (Test Results). The cover sheet includes the title 'Pre-Clinical Report', the test name 'Skin Sensitization Test', and the test results 'No adverse reactions observed'. The test results page includes a table with columns for 'Test Item', 'Test Method', 'Test Result', and 'Test Date'. The test results are summarized as 'No adverse reactions observed'.

It does not cause skin sensitization reactions

Certifications

LUCA AICell has obtained the Medical Device Certificate of GMP and ISO13485:2016.



Certifications

This is to certify that LUCA AICell has obtained US FDA Registration & Listing Clearance on the device below.



Certifications

This is to certify that LUCA AICell has obtained US FDA Registration & Listing Clearance on the device below.

The screenshot shows the FDA's public database for medical device registration and listing. The page is titled "Establishment Registration & Device Listing" and includes a breadcrumb trail: FDA Home > Medical Devices > Databases. A search bar at the top right allows users to follow the FDA or view the site in Spanish. The main content area displays the details for a specific device, with a "New Search" button and a "Back To Search Results" link. The device information is as follows:

Proprietary Name:	LUCA V-Defense Nasal Spray, NS01-20LF
Classification Name:	NASAL SPRAY, ENT DELIVERY
Product Code:	KCO
Device Class:	1
Regulation Number:	874.5220
Medical Specialty:	Ear Nose & Throat
Registered Establishment Name:	LUCA AICELL
Registered Establishment Number:	3022764539
Owner/Operator:	LUCA AICell
Owner/Operator Number:	10085130
Establishment Operations:	Manufacturer

At the bottom of the page, it states "Page Last Updated: 01/09/2023" and provides a note about accessing information in different file formats. It also lists language assistance options: Español, 繁體中文, Tiếng Việt, 한국어, Tagalog, Русский, العربية, Kreyòl Ayisyen, Français, Polski, Português, Italiano, Deutsch, 日本語, and English.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=818572&lpcd=KCO>

Certifications

LUCA AICell has obtained European CE MDR certification.

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 証書 証明書

EC

REP

CERTIFICATE
ECREP20230131.3
Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

LUCA AICELL, Inc.
11-35, Simin-daero 327beon-gil 3rd FL, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive/regulation and standard mention in Annex I of this certificate, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all below mentioned models of the medical device.

These products included in the Annex I have been registered in the Spanish MOH (AEMPS) if applicable. In this case, the column categorized as RPS refers to their registration number.

CE

Authorized signature

Issue date: 31/01/2023

Expiration date: 19/01/2024

CMC Medical Devices & Drugs S.L.
 C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification code

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 証書 証明書

EC

REP

CERTIFICATE
ECREP20230131.3
Ver: CERT-202110.V1

ANNEX I

Product Name	REGULATION	CLASS	RPS	Status RPS
LUCA V-Defense Nasal Spray	MDR	Class I	RPS/171/2023	Registered with AEMPS

Issue date: 31/01/2023


Expiration date: 19/01/2024

CMC Medical Devices & Drugs S.L.
 C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification code

Certifications

LUCA AICell has obtained import and marketing authorization from the Thai FDA.


แบบ จ.จ.น. ๑

ใบรับจดแจ้งนำเข้าเครื่องมือแพทย์

ใบรับจดแจ้งที่ 65-2-3-2-0005928

ใบรับจดแจ้งฉบับนี้ให้ไว้แก่

บริษัท เอ็มแอล (ไทยแลนด์) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 17/2562
เพื่อแสดงว่าเป็นผู้จดแจ้งนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๙ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑
และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

ลูกา วี-ดีเฟนซ์ นาซอล สเปรย์
LUCA V-DEFENSE NASAL SPRAY

รายละเอียดเครื่องมือแพทย์ ตามเอกสารแนบท้าย


ชื่อและที่ตั้งของสถานที่ผลิต ตามเอกสารแนบท้าย

ณ สถานที่นำเข้าเครื่องมือแพทย์ชื่อ บริษัท เอ็มแอล (ไทยแลนด์) จำกัด
ตั้งอยู่เลขที่ 283/48 ถนน สุขุมวิท 55 ถนน สุขุมวิท หมู่ที่
ตำบล/แขวง คลองตันเหนือ อำเภอ/เขต วัฒนา จังหวัด กรุงเทพมหานคร
รหัสไปรษณีย์ 10110 โทรศัพท์ 08 1195 6947 โทรสาร

ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์
LUCA AICELL, INC. - 11-35, Simin-daero 327 beon-gil, 3rd FL, Dongan-gu, Anyang-si, Gyeonggi-do, 14055,
Republic of Korea

ใบจดแจ้งฉบับนี้ใช้ได้จนถึงวันที่ 11 เดือน เมษายน พ.ศ. 2570 และให้ใช้เฉพาะสถานที่
ซึ่งระบุไว้ในใบรับจดแจ้งไว้เท่านั้น

ออกให้ ณ วันที่ 12 เดือน เมษายน พ.ศ. 2565



(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา
(ตำแหน่ง) กระทรวงสาธารณสุข
ผู้อนุญาต

เอกสารแนบท้าย

ใบรับจดแจ้งนำเข้าที่ 65-2-3-2-0005928

รายละเอียดเครื่องมือแพทย์

LUCA V-DEFENSE NASAL SPRAY (NS01-20LF) - ขนาด 20 ml

มีรายละเอียดรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
4542327000000	LUCA V-DEFENSE NASAL SPRAY	NS01-20LF	LUCA AICELL, INC. (KOREA) 11-35, Simin-daero 327 beon-gil, 3rd FL, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea Anyang-si Gyeonggi-do KOREA 14055	ขนาด 20 ml

Package Information

Box Package Information

Model#	Product Name	Product Box Info		RRP Box Info			Carton Box Info			
		Size(mm)	Weight(g)	Q'ty(EA)	Size(mm)	Weight(Kg)	Q'ty(EA)	Q'ty(RRP)	Size(mm)	Weight(Kg)
NS01-20LF	LUCA V-Defense Nasal Spray	35x35x115	40	10	185x75x119.5	0.435	180	18	575x480x140	8.50

Shipping Information

Container Size & Type	CT/Pallet	Pallet size(cm)	Pallet/Container	Q'ty on the Pallet (EA)	Additional Q'ty in CT (EA)	Total Q'ty (EA)	Total Weight (Kg)
20FT Reefer Container	52	110x110x211	8	74,880	15,120	90,000	4,298
40'HQ Reefer Container	60	110x110x242	20	216,000	12,240	228,240	10,898
20FT Container	52	110x110x211	10	93,600	-	93,600	4,480
40'HQ Container	60	110x110x242	20	216,000	24,480	240,480	11,476

LUCA V-Defense Nasal Spray

주식회사 루카에이아이셀 (LUCAAICell Inc.)

✉ sales@lucaaicell.com

🏠 3rd floor, 11-35, Simin-daero 327beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14055, Republic of Korea

☎ 031-8091-1000

📠 031-8091-0010

