

Public Comment 20-0526



EDC COB <edc.cob@edcgov.us>

BOS RCV'D 9/16/2020

COVID-19 EXPERT CONTACT: Dr. Ann Cornell-Bell - 3 PPT Files (2a) f/ TERRY KAYES

1 message

Terry Kayes <kayes.gov@gmail.com>

Tue, Sep 15, 2020 at 7:37 PM

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Greetings,

On Sunday or Monday, 9/13-14/2020, you should have received an email message from me titled 'COVID-19 EXPERT CONTACT: Dr. Ann Cornell-Bell (1a).' That e-message included her contact information, and some comments about her and the COVID-19 pandemic from me (particularly about the dangers of relying on only one or very few sources of expert knowledge).

Below (*as attachments*) are copies of three separate PowerPoint presentation files that she emailed to me on Tuesday, 8/25/20, about the COVID-19 'point of care Rapid Test,' 'new technology masks,' and 'new disinfection technologies.' Keep in mind that the information provided in these presentations may be somewhat dated and limited as to technical details. For information and insights on the COVID-19 pandemic, as well as details on the effectiveness of various newer up-to-date testing methods and protection technologies, contact Dr. Cornell-Bell. She has the expertise needed to provide such information and insights far more so than the overwhelming majority of sources.




If I can answer any questions, please don't hesitate to call or email me. (I can often help especially with 'valid' [vs. invalid] interpretation of reported statistical data, valid and verifiable biochemical and immunochemical testing protocols, and the general history of epidemics and how they 'evolve' over time in human populations [i.e., the consequences of mythologies, ignorance, denialism, self-destructive fear and anger, etc.].)

Be advised that the most recent trends in tracking the COVID-19 pandemic indicate it will be getting worse in the months of October and November, especially in more suburban and rural areas and the towns and smaller cities of California -- plus a number of other states in the West, Midwest and the South (raising major concerns about what will happen over the Holiday Season and beyond).

Best regards.

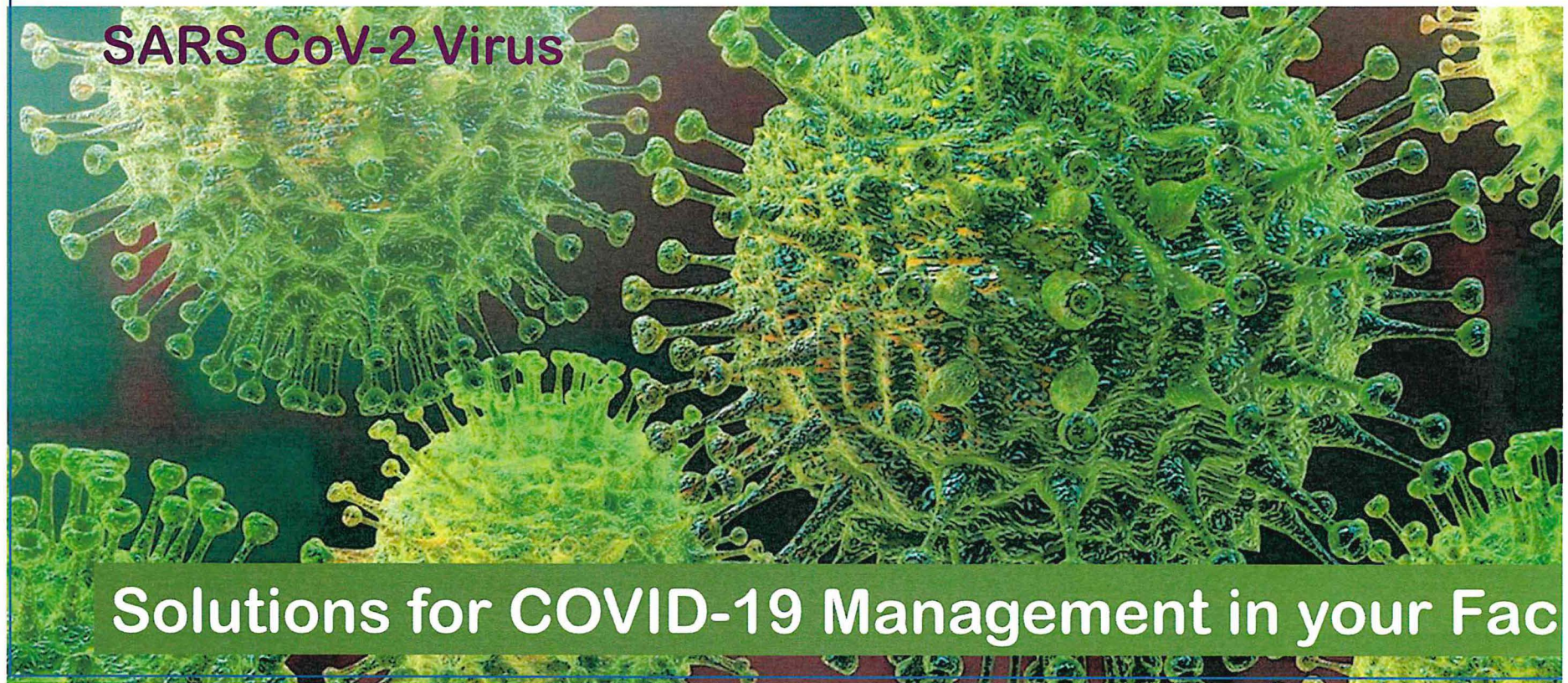
Terrence B. Kayes, PhD
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Placerville, CA 95667
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Mobile: 530-651-3461
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3 attachments

-  **MULTI-G CV-19 INTRO 8.23.20 (1).pdf**
2461K
-  **BMT MASK INTRO 8.23.20 (1) (1).pdf**
470K
-  **GERM MAGIC INTRO 8.23.20 (2).pdf**
770K

COVID19CHECK-MG from Multi-G BVBA

Serology Rapid Test for Detection of COVID-19 Antibod



SARS CoV-2 Virus

Solutions for COVID-19 Management in your Fac



Welcome to Multi-G:
<https://covid19check-mg.com/>

<https://images.app.goo.gl/WzoDp8Qh>

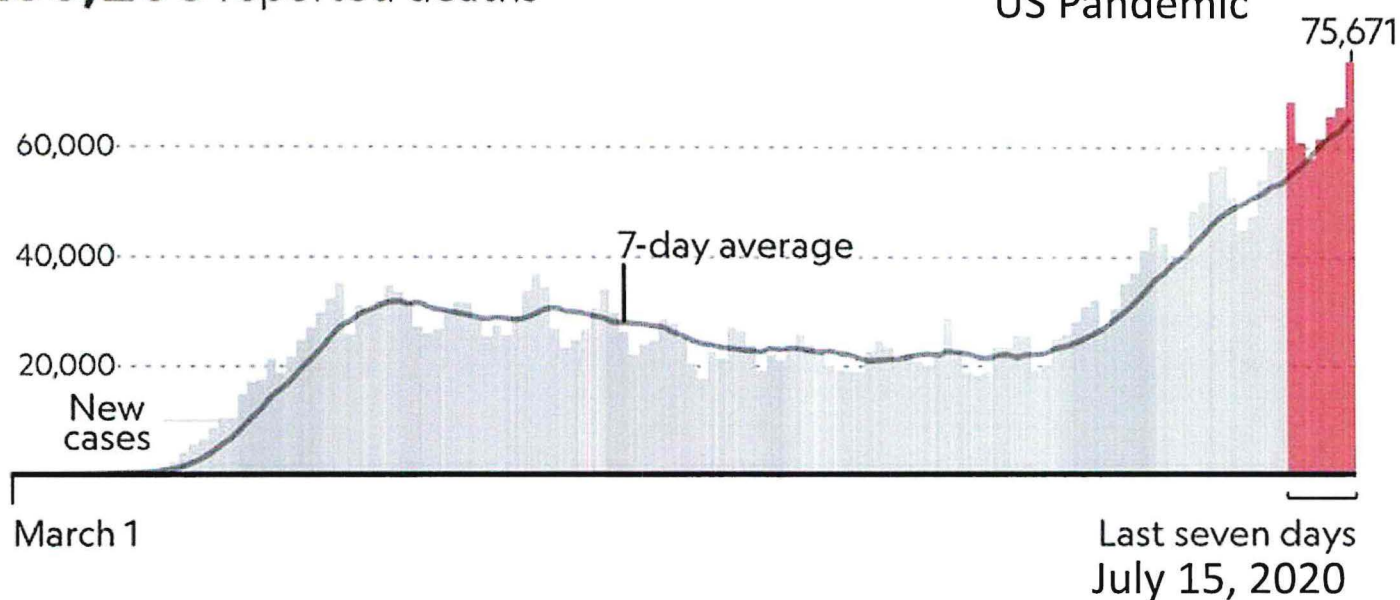
COVID-19 Confirmed Cases in the US are Climbing at an Alarming Rate

New daily confirmed coronavirus cases in the U.S.

3,588,462 total cases

138,268 reported deaths

Higher than at any point to date in the US Pandemic



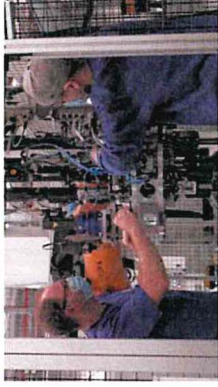
COVID19 is not going away. The US needs to learn to manage the virus in order to keep employees, students and family members safe!

Detect/ Protect/ Disinfect

Oasis Therapeutics, Exclusive Importer for Multi

Offers you COVID-19 Safety Solutions for

your business, school or your community



The World Health Organization in 2019 Suggested **Point of Care Treatment of COVID-19 is im** because:

- Rapid and accurate Point of Care Tests (POC) can b
where you need them
- POC tests enable early detection of infected patient
- Identification of COVID-19+ patients allows for isola
sick individuals from healthy individuals

Growing Need for Rapid Point-of-care Tests

“Development of rapid and accurate point-of-care tests which perform well in field settings are especially useful...”

This would markedly improve early detection and isolation of infected patients and, by extension, identification of contacts.”¹

**Separating COVID-19+
away from healthy pati
14 days slows new infe
a home, business, schc
the community.**

Detect The Multi-G COVID19CHECK-IgM/IgG Antibody Test Answers all WHO Cri

COVID19CHECK-MG is an **Inexpensive/Rapid POC Test**

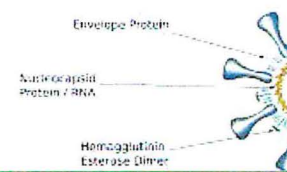
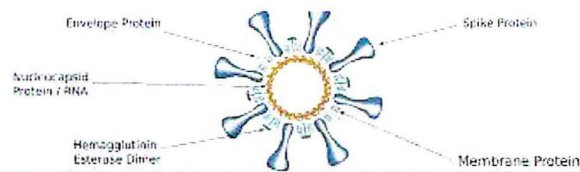
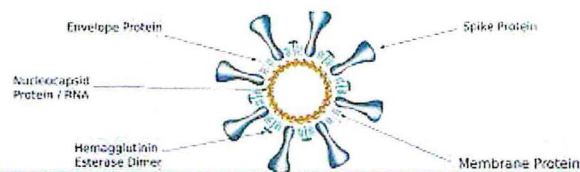
- Uses a Fingertick/Drop of Blood
- Answer within 10-15 minutes Incubation



Test Sampling **Method is Less Invasive** than:

- Nasal Swab PCR Test
- Blood Draw at a CLIA lab for Virus ELISA test
- Same method is used for daily blood sugar testing for Diabetes

This test is **ideal for screening large numbers of people** or repeat (1-2 x per week) as advised for some colleges, schools or businesses. **19+ cases are referred to a RT-PCR test** (Nasal Swab) or a virus assay performed by a Healthcare Provider ; registered Phlebotomist, Lab Tech, Nurse, Physician



COVID19CHECK-MG IgM/IgG Ab Test

- The test detects antibodies to SARS-CoV-2
- Differentiates between two antibodies (IgM and IgG)

Manufacturer: MULTI-G BVBA

Lange Leemstraat 166, 2018 Antwerpen, Belgium.

Management : GADY ZOHORI, CEO

Exclusive US Distributor: Oasis Therapeutics, LLC.

US Agent: Ann Cornell-Bell, PhD.

Email: ann.cornellbell@gmail.com

Tel: Office 860-399-9619

Cell 860-395-7645

Website: <https://covid19check-mg.com/>

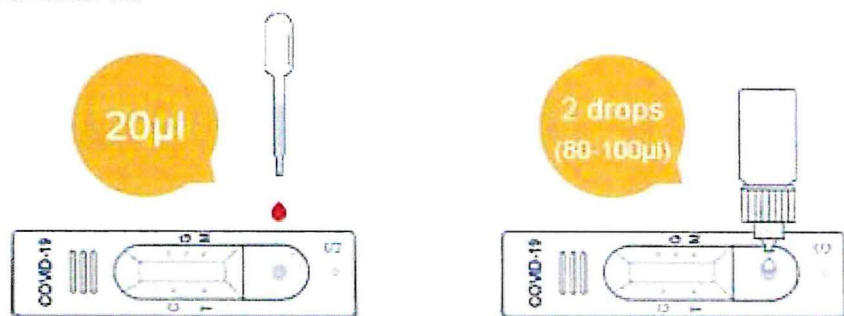
FDA Approvals to Multi-G for COVID19CHECK-MG

- Multi-G registration (# 3017035783) and owner/manufacturer (10074122)
 - The Multi-G COVID19CHECK-MG Rapid Test met the criteria established by the FDA (CDRH) as a “validated serological test for the presence of antibodies to COVID-19.”
 - Permission was granted to distribute this product in the United States under an Emergency Use Authorization (EUA) was reviewed.
 - FDA Center for Devices and Radiological Health received the submission on 5/7/20. EUA201086
-
-

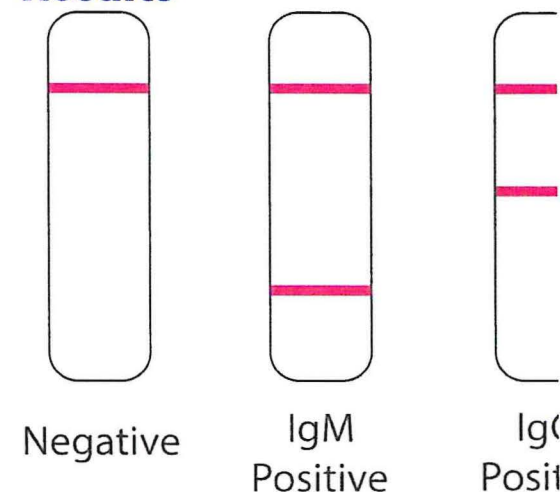
Instructions for Use - Multi-G COVID19CHECK-MG Ab

For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well upwards.
2. Add 20 μ l of whole blood vertically into the sample well.
3. Add two (2) drops (80-100 μ l) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes. The result is invalid after 20 minutes.



Results



IgG POSITIVE: Two distinct red lines appear. One line in the control region (C) and another line in the G test region, indicating IgG positive.

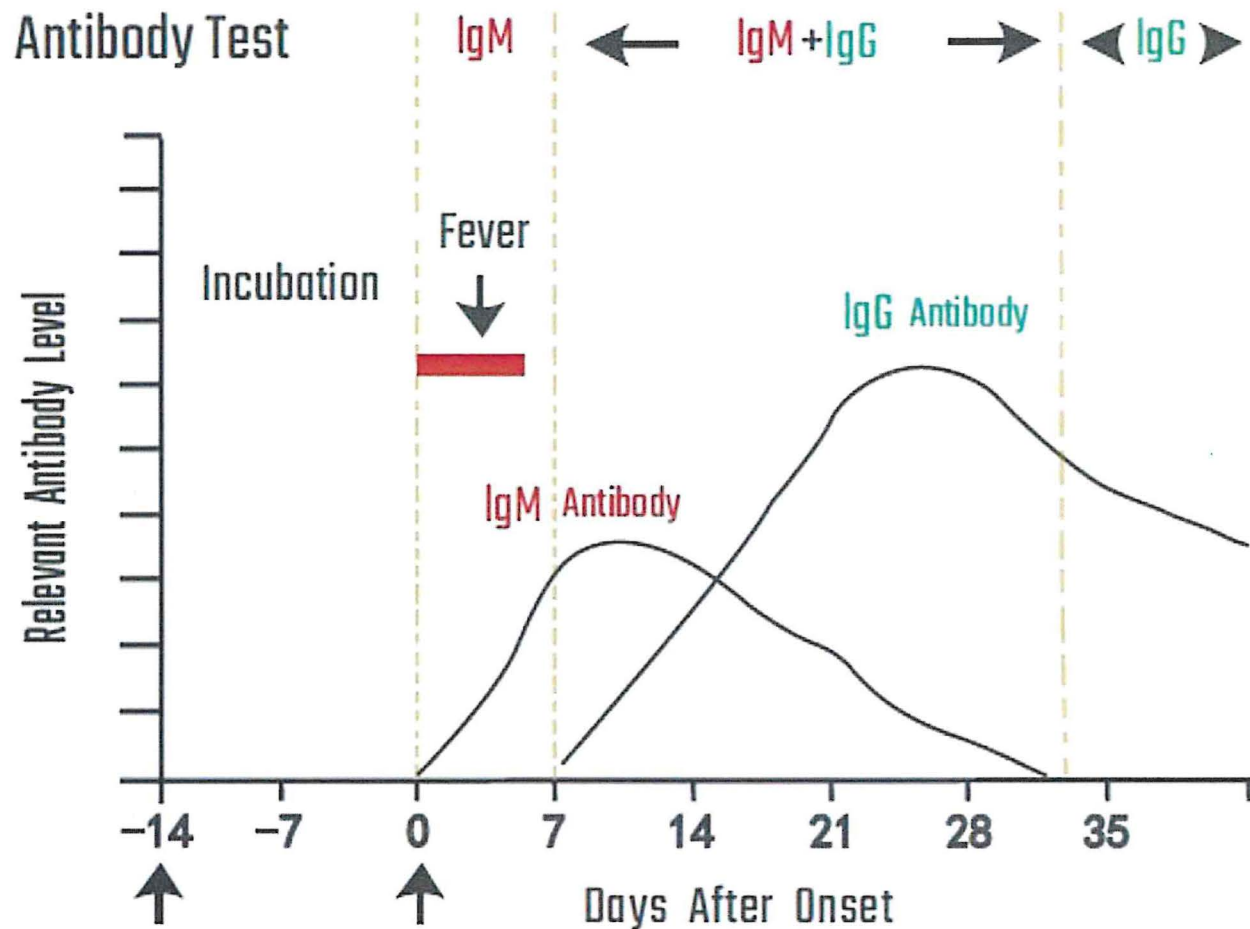
IgM POSITIVE: Two distinct red lines appear. One line in the control region (C) and another line in the M test region, indicating IgM positive.

IgG AND IgM POSITIVE: Three distinct red lines appear. One line in the control region (C), one in the G test region and one in the M test region (T2), indicating the IgG and IgM are positive.

NEGATIVE: One red line appears in the control region (C). No red or pink line appears in the test regions.

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

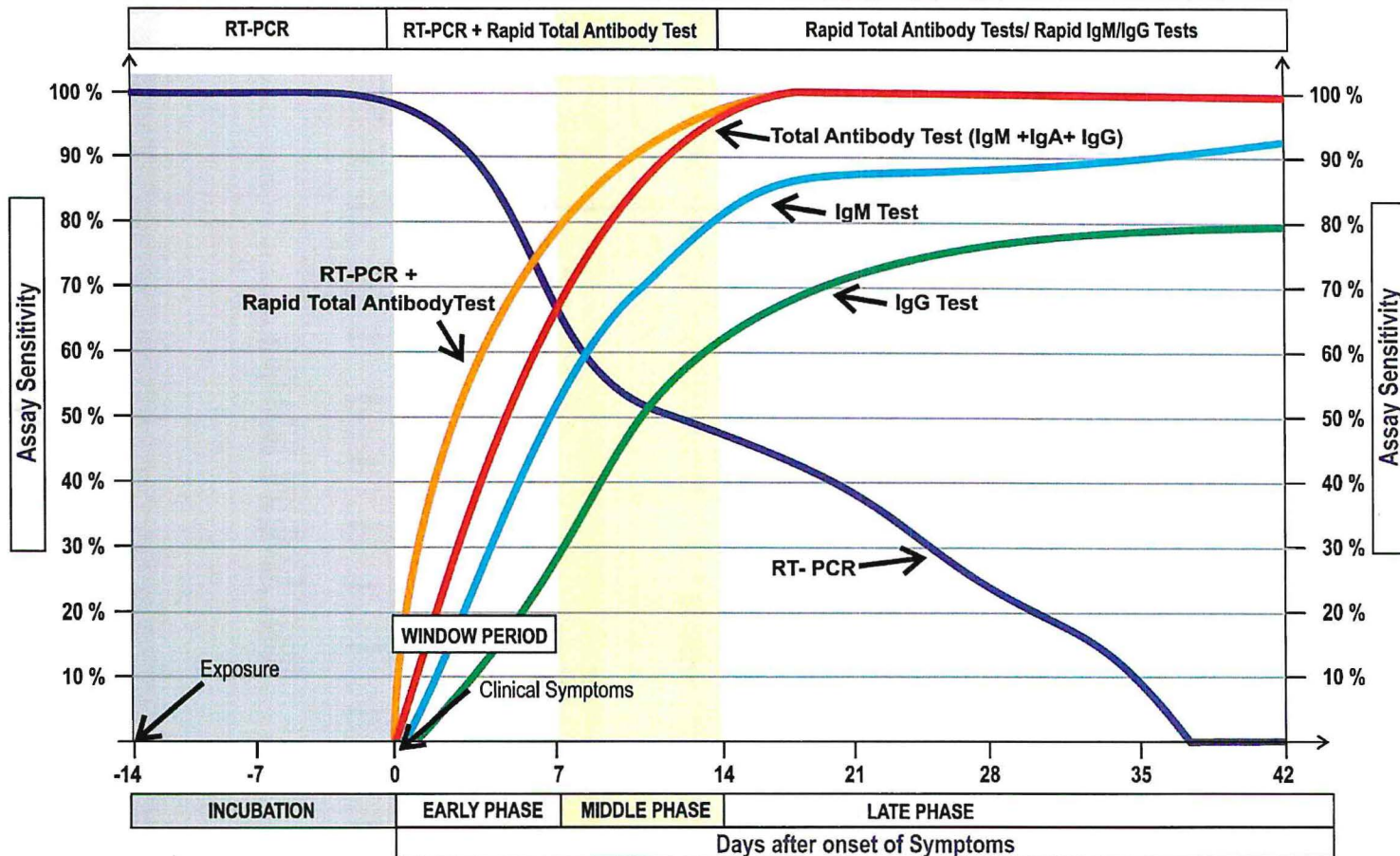
Timing of IgM and IgG Antibody Appearance Follow Virus COVID-19 Infection



- COVID19CHECK Establishes Presence of Antibodies to SARS-CoV-2
- To establish presence of virus on any given day, a PCR test or ELISA for specific virus protein is required
- The SARS CoV-2 is cleared from a patient in 7-10 hrs so the virus-only accounts for the initial positive result
- The serology analysis provides a historical record of virus production over time

COVID-19 TRIAGING OF SYMPTOMATIC PATIENTS

TYPICAL CLINICAL SYMPTOMS: "Fever, Dyspnea, Fatigue, Dry Cough, Myalgia, Lymphopenia and radiological findings of pneumonia." [2]



- The RT-PCR (Reverse Transcription Polymerase Chain reaction) test is most sensitive in the early phase of COVID-19 infection
- By day 3 of symptoms, antibodies are circulating. Sensitivity increases over the next 21 days.
- By day 7, IgG is undetectable and increases over the next 14 days.
- By day 10, RT-PCR sensitivity drops to 50%, a false negative

**By the Middle Phase of the Infection the RT-PCR test has decreased to 50% Sensitivity
Resulting in increase in false positives results**

COVID19CHECK-MG Rapid Antibody Test Offers Great A

Serology Tests increase your ability to keep pe

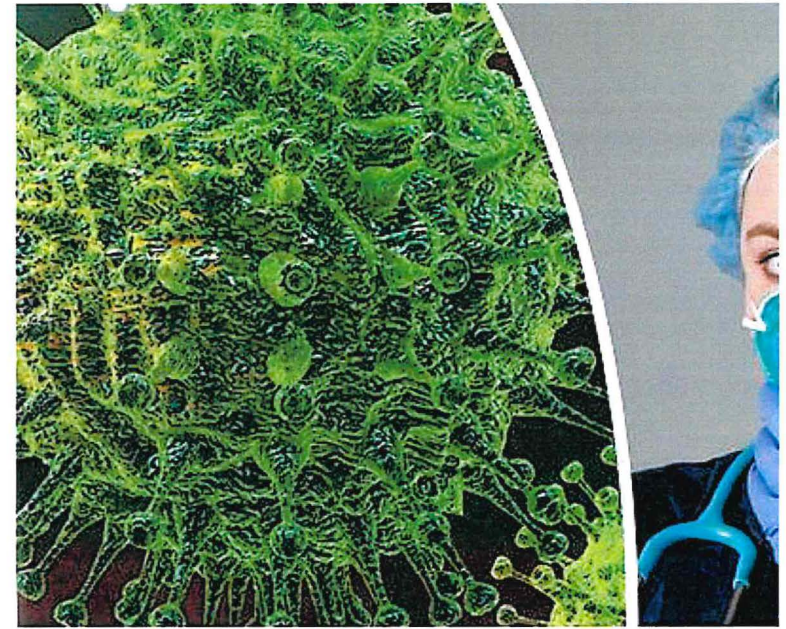
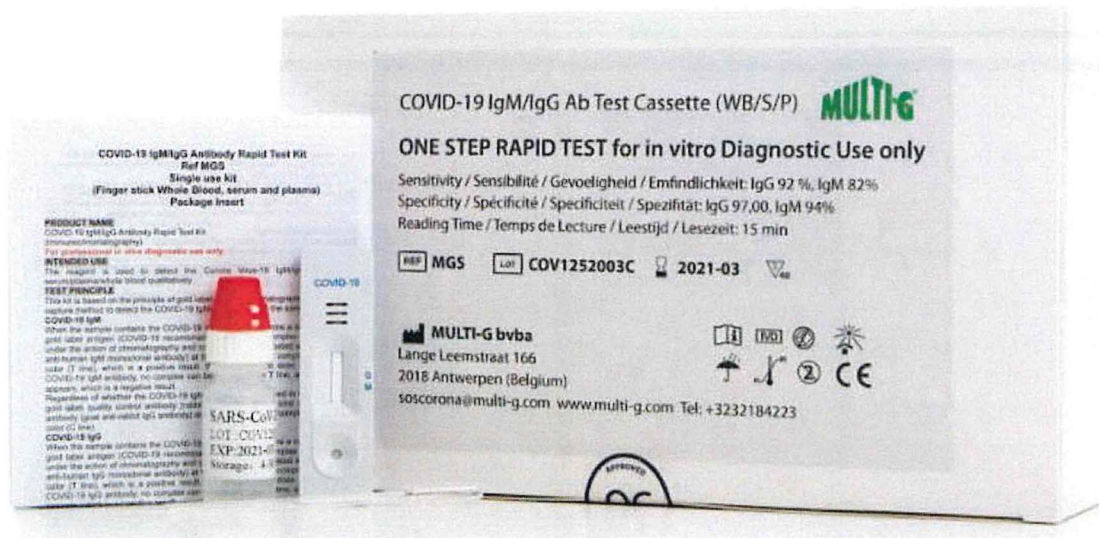
- This is a point of care test: no lab required
- **Lower your costs of 1st pass screens** for COVID-19
- Quickly identify COVID-19-free cases
- **Send only positive cases on for RT-PCR, Nasal Swab Test**
- Save money on PCR swabs and chemicals for COVID-19+ c
- **ID Asymptomatic people** producing antibodies to SARS Co
- Capture COVID-19 antibody production history over 40 day
- **Less burdensome method**
- Employer testing would reduce potential exposure to worl
claims that could arise within the workplace



How to Purchase COVID19CHECK-MG IgM/IgG ,

- Determine the number of test units required
- Multi-G's US exclusive importer, Oasis Therap will send a Proforma Invoice including:
- Bill of Lading including all shipping costs
- 50% payment due upon placement of your order
- 50% payment due upon shipping your order
- Shipped directly to the end user

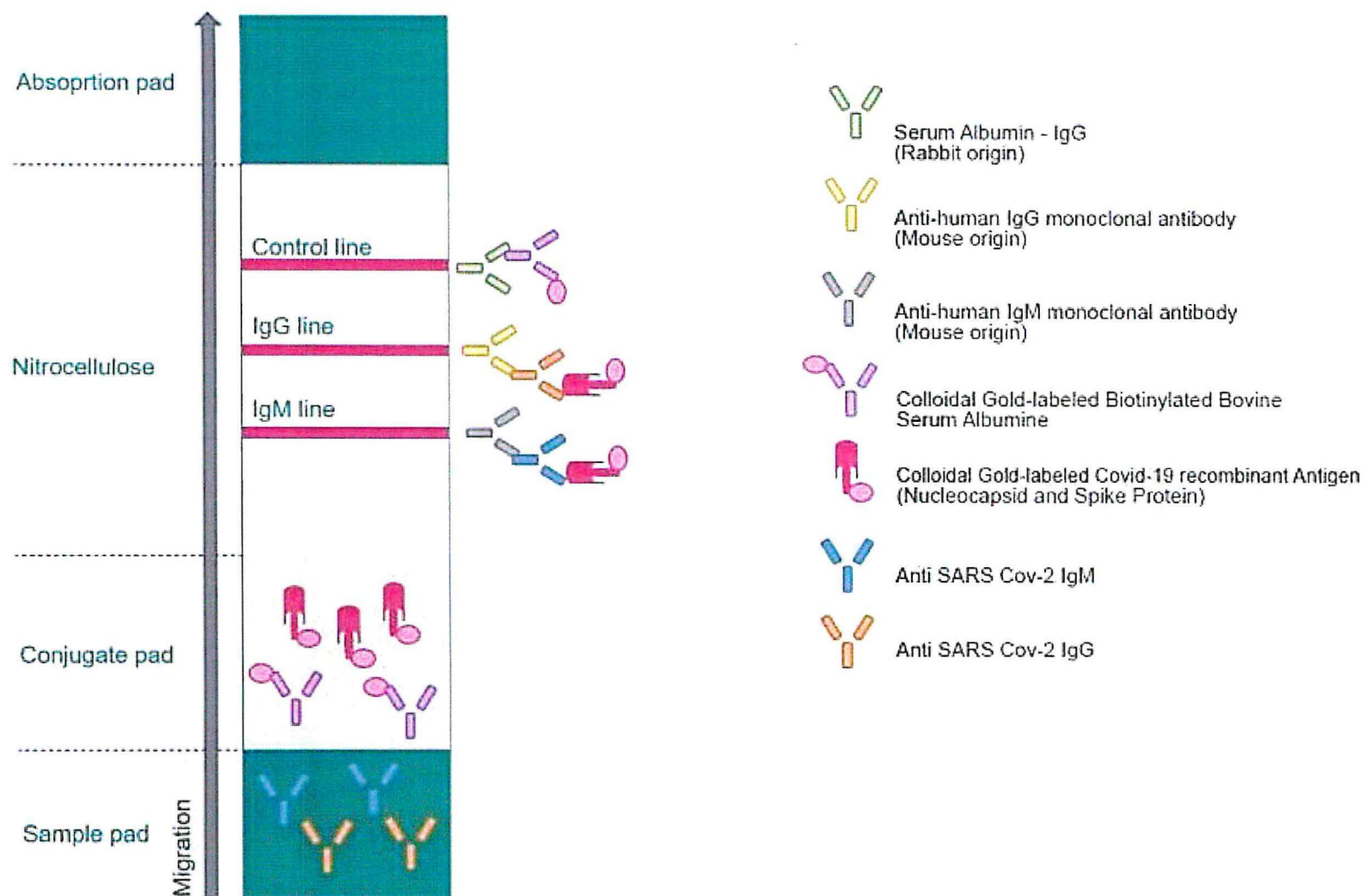
Ann Cornell-Bell, PhD US Agent will answer any questions on the COVID19CHECK-MG Test



Details and Validation of the COVID19CHEC Rapid Antibody Test - Scientific Addendur

Multi-G COVID19CHECK-MG Antibodies Show High Sensitivity and Specificity for SARS CoV-2

SCHEMATIC DESCRIPTION



COVID19CHECK-MG IgM/IgG Ab Test Compared to PCR

Clinical Trial has 300 positive patients and 1000 negative patients

Age	Gender	Result		
		IgG	IgM	PCR Results
83	Male	+	-	+
65	Female	+	+	+
59	Female	+	+	+
48	Female	+	+	+
36	Male	+	+	+
81	Female	+	+	+
85	Male	+	+	+
39	Male	+	+	+
84	Female	+	+	+
91	Male	+	+	+
39	Male	-	-	-
80	Female	-	-	-
96	Female	-	-	-

Polymerase Chain Reaction (PCR Test) is usually used with the nasal swab

- Results of the IgM/IgG a were compared to resul PCR Test
- Coincidence compares results from treatment g correspond
- The Coincidence for 30(samples for **IgM** test vs is 82%
- The Coincidence for 10(samples for **IgM** vs PCR
- The Coincidence for 30(samples for **IgG** test vs. 93%
- The Coincidence for 10(samples for **IgG** test vs.
- **Coincidence for all IgM. PCR is 93% (combined s**
- **Coincidence for all IgG. is 97%**
- ❖ Fraction of samples e from the clinical trial

Performance Evaluation for the Detection of anti SARS-CoV-2 Antibodies Presented by 1 The French National Centre for Scientific Research, (Paris or Lyon) Respiratory infectious virus (including flu) and validation by health authorities

COVID-19 IgM/IgG Antibody Rapid Test Kit

Multi-G Is the Manufacturer

Date of the Report 6/18/2020

Name of the Rapid Test

Sensitivity

IgM Samples 7-13 days post start of symptoms

67% [31% -91%] (9 samples)

IgM Samples 14-19 days post start of symptoms

75% [43% -93%] (12 samples)

IgM Samples at least 20 days post start of symptoms

42% [26% -59%] (33 samples)

IgM Specificity

100% [87%-100%] (34 samples)

IgG Samples 7-13 days post start of symptoms

67% [31% -91%] (9 samples)

IgG Samples 14-19 days post start of symptoms

83% [51% -97%] (12 samples)

IgG Samples at least 20 days post start of symptoms

91% [75% -98%] (33 samples)

IgG Specificity

100% [87% -100%] (34 samples)

Total IgM + IgG Samples 7-13 days post start of symptoms

78% [40% -96%] (9 samples)

Total IgM + IgG Samples 14-19 days post start of symptoms

83% [51% -97%] (12 samples)

Total IgM + IgG Samples at least 20 days post start of symptoms

91% [75% -98%] (33 samples)

Total IgM + IgG Specificity

100% [87% -100%] (34 samples)

Specificity is a measure for FALSE POSITIVES - SPECIFICITY of 100% MEANS ZERO FALSE POSITIVES.

Table: Clinical study result of INCP-402

IgG result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: >99,9% (95%CI*: 86% -100%)

Relative Specificity: 98,0% (95% CI*: 89,4% - 99,9%)

Accuracy: 98,6% (95% CI*: 92,3% - 99,96%)

* confidence Intervals

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85,0% (95%CI*: 62,1% -96,8%)

Relative Specificity: 96,0% (95% CI*: 86,3% - 99,5%)

Accuracy: 92,9% (95% CI*: 84,1% - 97,6%)

* confidence Intervals

Multi-G Rapid Test Statistics

Assay Statistics Compiled 2 Repeats

IgG Results

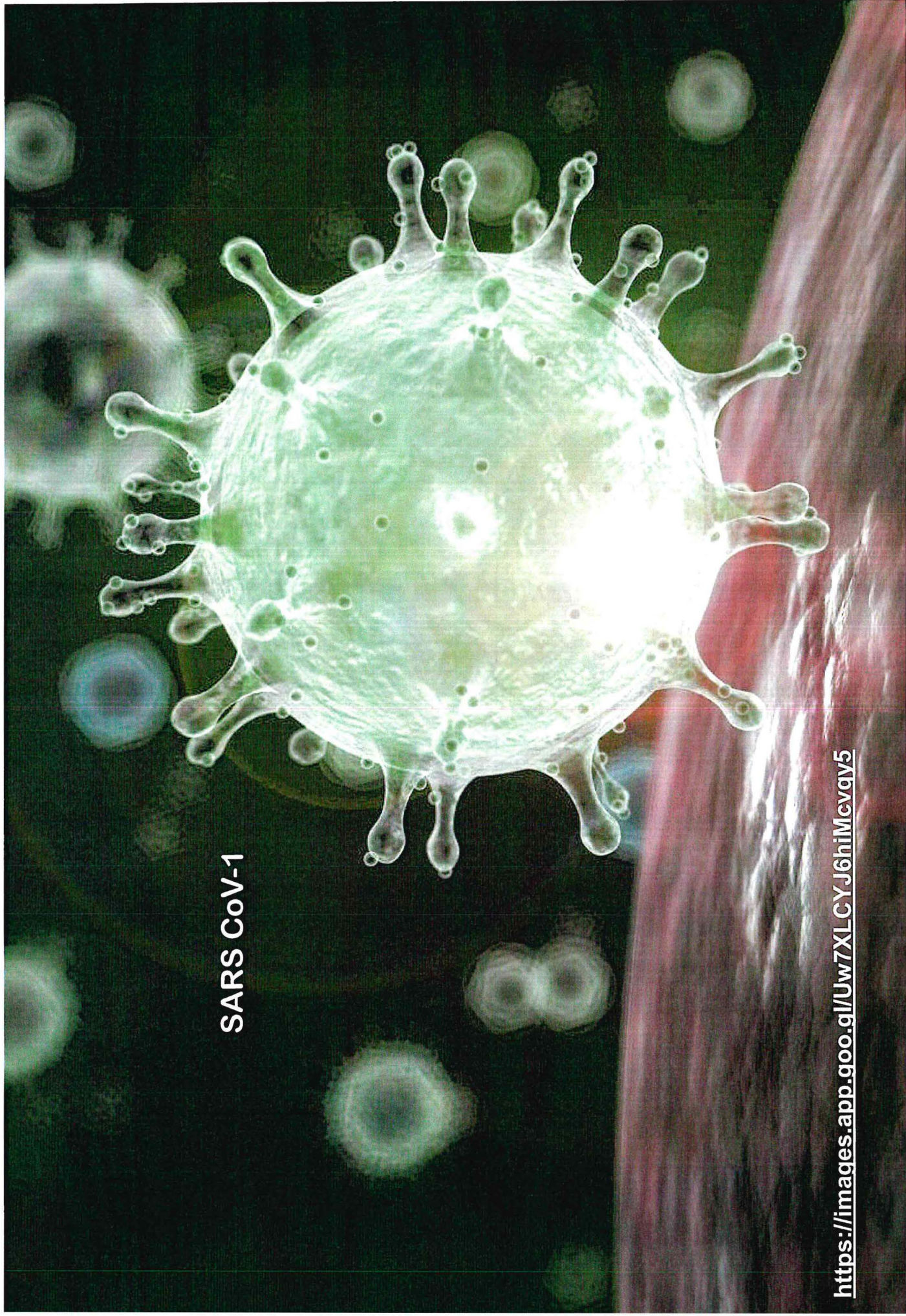
Relative Sensitivity: >99.9% (95%
New Specificity Data from FNCSR
Relative Specificity: 98.0% (95%
Accuracy: 98.6% (95% CI*: 92.3%

IgM Results

Relative Sensitivity: 85.0% (95%
New Specificity Data from FNCSR
Relative Specificity: 96.0% (95%
Accuracy: 92.9% (95% CI*: 84.1%

SARS CoV-1

<https://images.app.goo.gl/Uw7XLCYJ6hiMcvqy5>







**U.S. FOOD & DRUG
ADMINISTRATION**

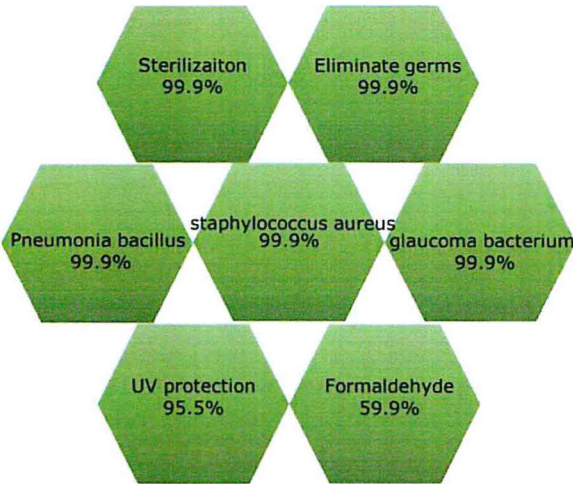
Reusable for 7 days

BMT BIO MASK

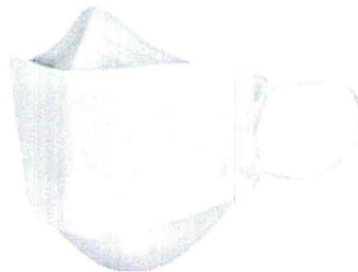
Anti-bacterial effect, Deodorization, UV protect

Protect

BMT Biomask



BMT BIO MASK



FDA U.S. FOOD & DRUG
ADMINISTRATION

7-day of use!



~~Disposable~~

Anti-bacterial

inside filter

BMT fabric

Qualified for FDA Human Body Testing



FDA U.S. FOOD & DRUG
ADMINISTRATION

Eliminates 99.9% of Germs

The BMT Mask is FDA Approved



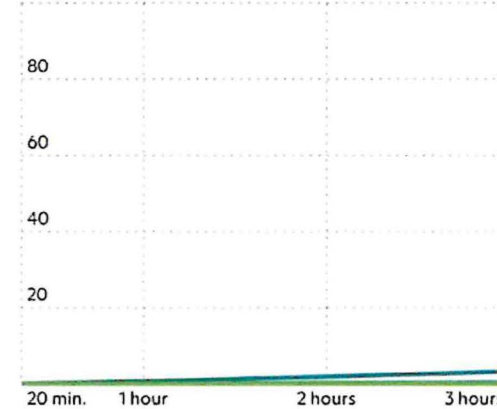
BMT fabric is colorless, odorless, safe for skin, and breathing

Masks are effective at limiting Cov infection based on mathematical r

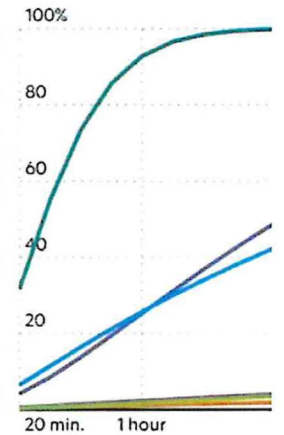
An indoor gathering An energy-efficient office A classroom lecture Strenuous c
 A subway ride A bus ride

In an airtight N95 mask...

100% likelihood of infection



...and with no masks.



Order BMT Masks through Oasis T 7 days wear

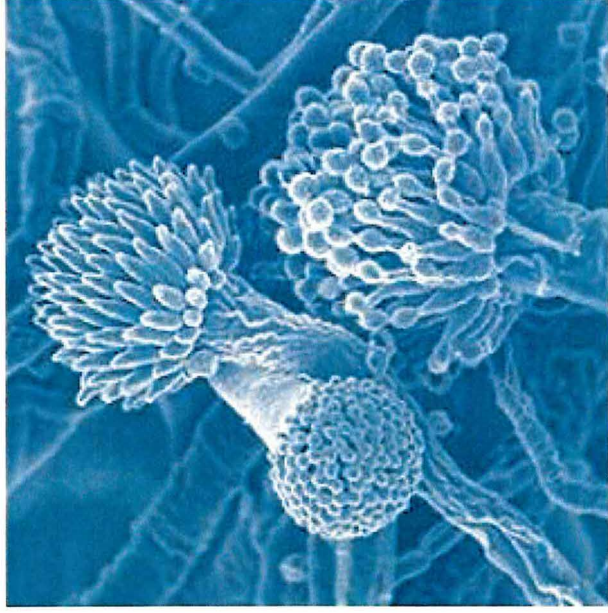
Bio Mineral Transplant Advanced Technology

2D a

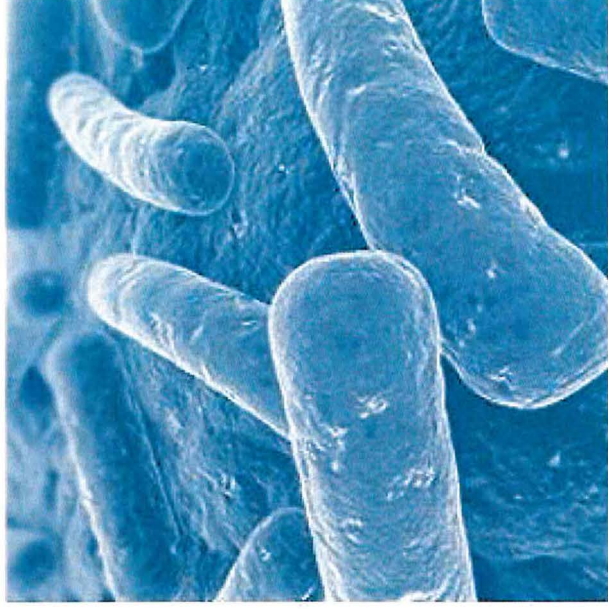


TECHNOLOGY OF GERMAGIC™

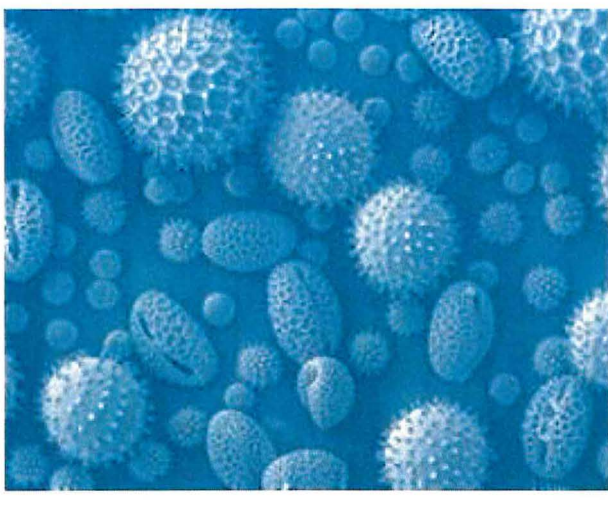
Disinfecting Agent Kills Fungi Bacteria and Viruses



Fungi



Bacteria



Viruses

Disinfect

Requires a Non-Disclosure Agreement

Germicidal Hepafilter



Germagic Disinfectin

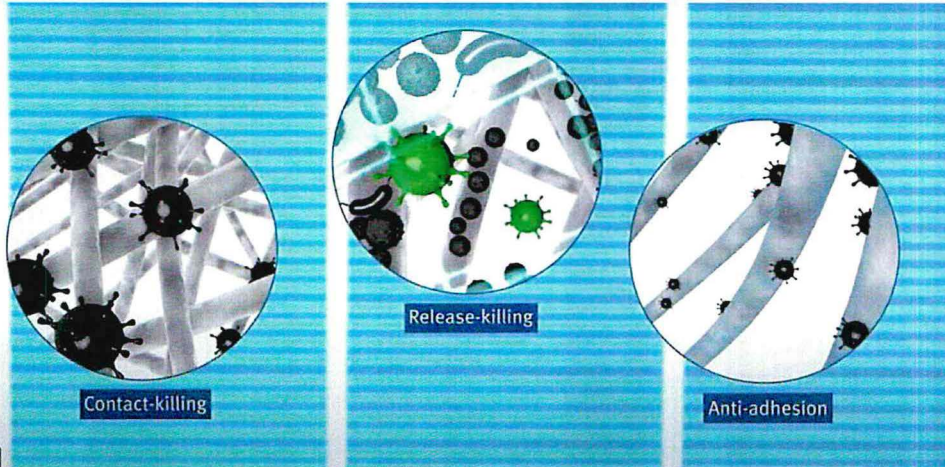
Natural Product

Germagic kills Viruses, Bacteria and Fungus Spores

VIRUS (30S CONTACT)	ELIMINATION RATE
MERS-COV	98.8% (60 MIN CONTACT)
H1N1 INFLUENZA A VIRUS	>99.999% (60 MIN CONTACT)
INFLUENZA B VIRUS	>99% (60 MIN CONTACT)
ENTEROVIRUS 71	>99% (30 MIN CONTACT)
H1N1 SWINE FLU OR NOVEL INFLUENZA A	>99.9% (60 MIN CONTACT)
H3N2 HONG KONG FLU VIRUS	>99% (60 MIN CONTACT)
H7N9 AVIAN INFLUENZA	>99.9% (60 MIN CONTACT)

SPORES (30 MIN CONTACT)

- B. SUBTILIS ENDOSPORES (99%)
- CLADOSPORIUM SPORES (99%)
- ASPERGILLUS SPORES (90%)
- PENICILLIUM SPORES (90%)



3 Kinds of killing:
Contact killing,
Release Killing and
Anti-Adhesion Killing

BAC

ESC

PSE

STE

SER

PSE

KLE

STR

STR

ELIG

MO

KOC

STA

BAC

CHF

LEC

PRC

PSE

ENT

STA

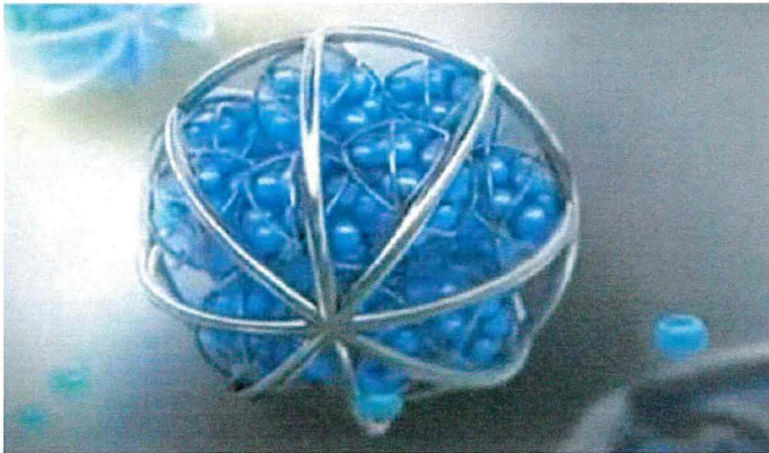
MO

PAS

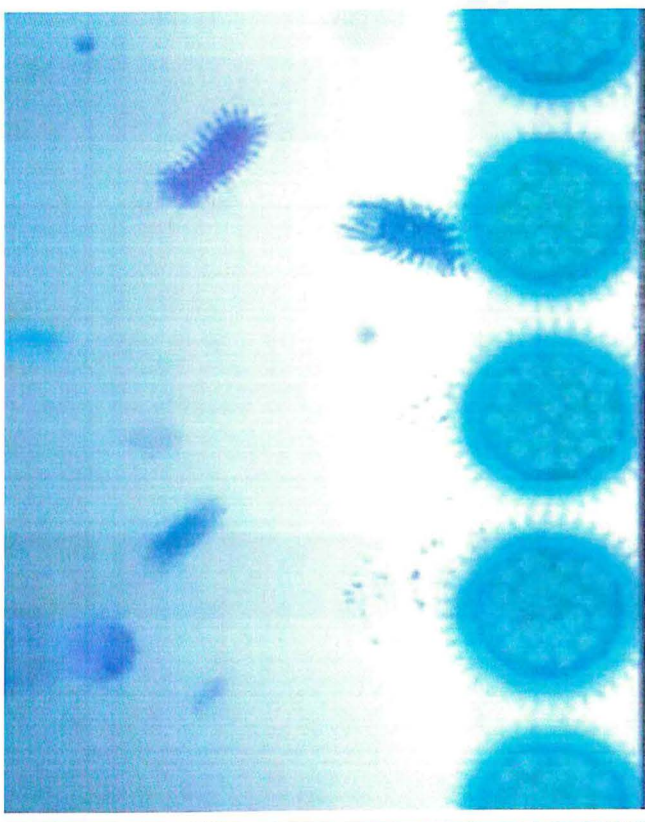
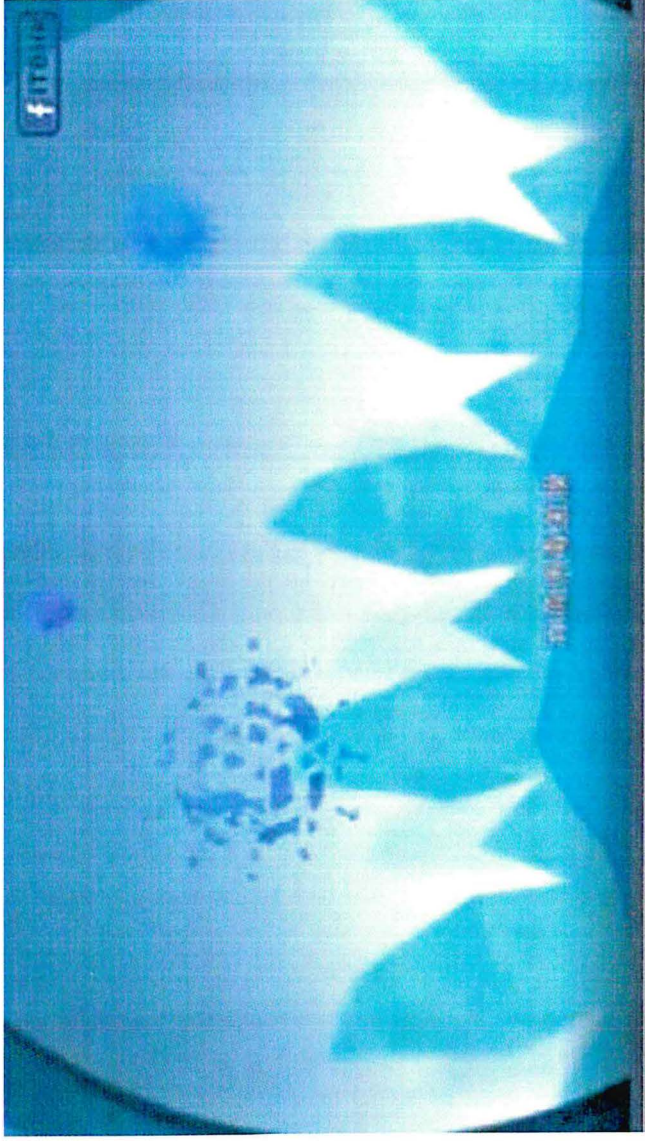
GERMAGIC COATING TECHNOLOGY

Germagic is a new sterilization technology:

- Created by Hong Kong University of Science & Technology (HKUST).
- Partnered with Jiehe Industrial Co., Ltd. (a billion dollar H.K. listed co
- Germagic was developed by HKUST scientists in response to SARS outbreak in Hong Kong (2003).
- 17 Years of R&D testing in China, Australia, the UK and the US.



Nanospheres release disinfectant in response to heat and pressure



Molds, Viruses and Bacteria are pierced and destroyed on contact. Nano-Capsules release disinfectant whenever they sense heat or from or from pressure.

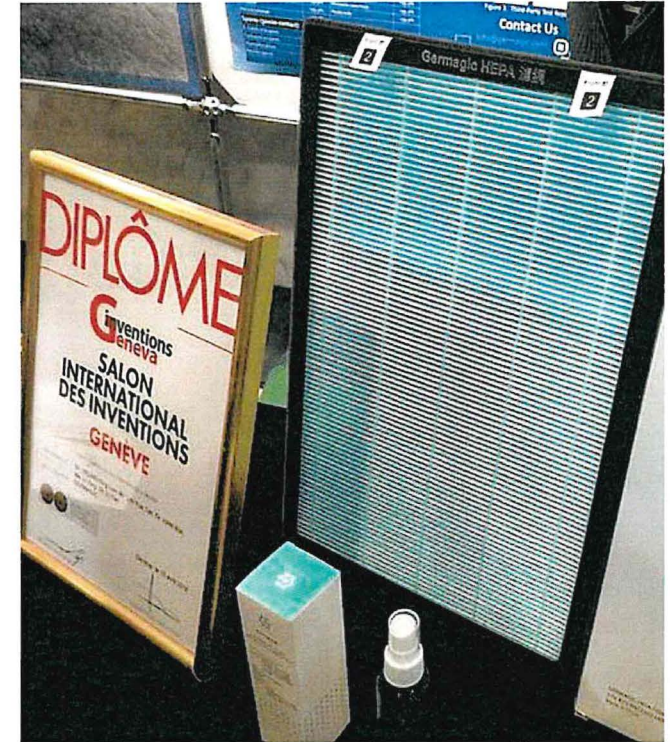
Purchase Germagic Products from Oasis Therap



72 Hour Disinfection



30 Days Disinfection



2 years Disinfect

2018 Winner of Geneva Invent

Germagic Electrostatic Sprayers



Adjustable nozzle for large applications including...

90 Day Disinfection