GLOBAL
INFECTION CONTROL CONSULTANTS LLC

April 18, 2020

COVID-19 And the Use of Path-Away

Attached is a copy of a lab report testing Path-Away Anti-Pathogenic Aerosol Solution® against the current COVID-19 (SARS-CoV2) virus spreading globally. This information is part of multiple tests on different organisms conducted simultaneously. I'd like to break this down for your understanding.

1. Page 2: You will note that Path-Away Anti-Pathogenic Aerosol Solution® was tested indicating two (2) distinct results. There is a listing for ***Feline coronavirus*** and ***COVID-19 (SARS-CoV2).*** The important distinction is that the ***COVID-19 (SARS-CoV2)*** in in fact a separate and distinct Genus/Species. There has been much confusion about this because a source of ***Feline coronavirus*** is listed. ***This is what is commonly conducted and accepted by testing authorities***.
2. Page 3: In the listing for "Test Information" you will see a line listed as "Test Concentrations." It is common to conduct these tests at different concentrations. It is important to understand that Path-Away Anti-Pathogenic Aerosol Solution®, for current field use is provided for use at the 3% concentration level. When diluted to lower concentrations as was done in the testing it does not meet the efficacy criteria for use on **COVID-19 (SARS-CoV2).** As indicated on pages 4-7 it clearly indicates success at the 3% concentration but not at the other dilutions performed bb the lab personnel. As long as you do not dilute the Path-Away Anti-Pathogenic Aerosol Solution® supplied to you the results will be successful against the **COVID-19 (SARS-CoV2) virus.**
3. Page 3: Section "Deviations from Standard Method." Non-standard ***Feline Coronavirus*** is the standard surrogate used for initial testing. Just as with testing Mycobacterium *tuberculosis,* the initial surrogate bacterium is Mycobacterium *smegmatis.* Initial tests are conducted against surrogates as a common laboratory technique. Surrogates typically contain similarly structured homologs and are less virulent and thereby allowing testing under less stringent conditions of laboratory design and protocol.
4. Page 3: Section "Test Results Summary." Here it is clearly stated that when used against **COVID-19 (SARS-CoV2)**, Path-Away Anti-Pathogenic Aerosol Solution® exceeds the minimum 4-log acceptable reduction to qualify for use.
5. Page 4: Efficacy at both 1-minute contact time and 5-minute contact time clearly shows Path-Away Anti-Pathogenic Aerosol Solution® exceeding the minimum 4-log acceptable reduction to qualify for use. Full 3% (Neat) concentration shows success

Regulatory Approvals

Much confusion exists concerning who says it is appropriate for use and where can it appropriately be used. The following proclamation issued by the United States Environmental Protection Agency (EPA) will clarify for you that Path-Away Anti-Pathogenic Aerosol Solution® meets current criteria for use on the ongoing **COVID-19 (SARS-CoV2)** situation.

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On January 29, 2020 *the United States Environmental Protection Agency (EPA) activated the "Emerging Viral Pathogen Guidance for Antimicrobial Pesticides" in response to the discovery of the novel coronavirus, SARS-COV-2. The guidance, issued in 2016, details a process by which companies holding current EPA registrations under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for certain disinfectant products can promote those products for use against "emerging pathogens" like the coronavirus.*

On January 12, 2015*, prior to this ruling, "Path-Away Anti-Pathogenic Aerosol Solution" was already declared "exempt from registration" by qualifying as a minimum risk pesticide as defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 25(b), outlined in title 40 of the Code of Federal Regulations (CFR), section 152.25, and in title 3, California Code of Regulations section 6147. Path-Away Anti-Pathogenic Aerosol Solution is an organic based solution certified with "Organic Input" with "no GMO" components and meets registration regulations on a global basis.*

Path-Away Anti-Pathogenic Aerosol Solution®, *registered with the United States of America Patent and Trademark Office, #4,032,774, was scientifically developed by Arthur V. Martin, Ph.D., president of Global Infection Control Consultants, LLC. It is a broad spectrum anti-pathogenic product with proven efficacy against 170+ individual pathogens including a wide range of fungi, bacteria, yeasts and viruses including H1N1, Mycobacterium tuberculosis, Influenza and others. Path-Away Anti-Pathogenic Aerosol Solution received this rare exemption due to its high efficacy combined with extremely low toxicity. It has been successfully and safely utilized in numerous consumer products as an anti-bacterial agent. Path-Away Anti-Pathogenic Aerosol Solution is available through a very select group of globally based representatives. Contact our office (amartin@gicclc.com) for the representative near you.*

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Study Title:
Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1)

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Gollinrod, Walmersley, Bury, BL9 5NB, UK

Angela Davies, CEO

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Scope

The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of a chemical disinfectant and antiseptic products that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances. This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European standard applies to areas and situations where disinfection is medically indicated. Such indication occurs in patient care, for example: In hospitals, in community medical facilities and in dental institutions or in clinics of schools, of kindergartens and of nursing homes, and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for patients.

Outline of Test Method (Obligatory Test Conditions)

A sample of the test product is diluted in synthetic hard water in products diluted at point of use or water in the case of ready to use products is added to a test suspension of viruses in a solution of interfering substance. The mixture is maintained at one of the temperatures and contact times specified in the standard. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilutions of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Käber or by plaque counting. Reduction of virus infectivity is calculated from differences of lg virus titres before (virus control) and after treatment with the product. The standard minimum spectrum of test organisms is Poliovirus, Adenovirus and Murine Norovirus.

Acceptance Criteria

The product when tested as above shall demonstrate at least a 4 $\log_{10}$ reduction against the test virus. The test is deemed valid where all control requirements are met.

Other notes

	Feline coronavirus	**COVID-19 (SARS-CoV2)**
Realm	Riboviria	Riboviria
Order	Nidovirales	Nidovirales
Family	Coronaviridae	Coronaviridae
Genus	Alphacoronavirus	Betacoronavirus
Species	Alphacoronavirus 1	COVID-19

The members of the family Coronaviridae are enveloped and have a positive sense RNA genome. Coronaviruses have a distinct morphology with an outer 'corona' of embedded envelope spikes. These viruses cause a broad spectrum of animal and human disease.

Andrew M.Q. King, Michael J. Adams, Eric B. Carstens, and Elliot J. Lefkowitz 'Virus Taxonomy, Classification and Nomenclature of Viruses, Ninth Report of the International Committee on Taxonomy of Viruses' 2012 ISBN 9780123846846

Test information		Deviation
Name of Product	Path Away	
Batch Number & Expiry Date	N/S	
Date of Delivery	13/04/2020	
Period of Analysis	31/03/2020-06/04/2020	
Manufacturer / Supplier	Global Infection Control Consultants LLC	
Storage Conditions	Ambient	
Appearance of the Product	Colourless liquid	
Neutralisation Method	Dilution	
Product Diluent	Distilled water	
Test Concentrations	Neat as received (3%) , Mid-range (1.5%)Non active (0.1%)	
Experimental Conditions	Clean	
Interfering Substance	Clean 0.3g/l Bovine Albumin	
Test Temperature	20°C ± 1°C	
Temperature of Incubation	37°C ±1°C for 72hrs	
Identification of the Bacterial Strains:	ATCC VR-1508 Feline Coronavirus, Strain Munich. COVID-19 SARS CoV2)	*1*
Contact Times	1 & 5 Minutes ± 10 s	
Stability and Appearance During Test	No Change Observed (Homogenous)	

Deviations from Standard Method

1 – The product was tested against non standard organism Feline coronavirus, therefore reference inactivation controls were not performed due to no acceptance criteria available.

Test Result Summary

The test product received has achieved a >4-log reduction when tested under the condition stipulated in this report, against Feline coronavirus and COVID-19. SARS-CoV2 when tested at a concentration of neat(3%).

Summary Feline coronavirus

Controls					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	1 minute	8.04	N/A	Validated
Cytotoxicity (product)	Neat	N/A	2.50	N/A	Validated
Product supression control	Neat	Neat	7.79	0.25	Validated

Controls					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	5 minutes	7.71	N/A	Validated

Interference controls					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	Neat	N/A	8.67	N/A	N/A
Interference control (treated)	Neat	N/A	8.46	0.21	Validated

Test Results				
Condition	Concentration	Contact time	log TCID50	log reduction
Test product	Neat	1 minute	3.88	4.17
Test product	50%	1 minute	4.88	3.17
Test product	0.10%	1 minute	7.71	0.33

Test Results				
Condition	Concentration	Contact time	log TCID50	log reduction
Test product	Neat	5 minutes	3.38	4.33
Test product	50%	5 minutes	4.67	3.04
Test product	0.10%	5 minutes	7.63	0.08

Raw data

Virus control (water)				Contact time		5 minutes		
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	3	4	4	4	4	0.95833333	0.039931
-7	3	3	3	3	3	3	0.75	0.1875
-8	2	2	2	1	2	1	0.41666667	0.243056
-9	1	1	0	0	0	0	0.08333333	0.076389

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	3.21
n	8
SD50	-7.71
SE	0.28
xp	-5

Test product		Product concentration			Neat	Contact time		5 minutes
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	3	3	3	3	3	3	0.75	0.1875
-4	1	1	1	0	0	0	0.125	0.109375
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	1.88
n	8
SD50	-3.38
SE	0.21
xp	-2

Test product		Product concentration			50%	Contact time		5 minutes
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	3	3	0.91666667	0.076389
-5	2	2	1	1	0	0	0.25	0.1875
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.17
n	8
SD50	-4.67
SE	0.19
xp	-3

Test product		Product concentration			0.10%	Contact time		5 minutes
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	3	3	4	2	2	2	0.66666667	0.222222
-8	1	1	1	2	2	2	0.375	0.234375
-9	1	1	0	0	0	0	0.08333333	0.076389

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.13
n	8
SD50	-7.63
SE	0.28
xp	-6

Raw data

Virus control (water)				Contact time		1 minute		
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	3	3	4	4	4	4	0.91666667	0.076389
-8	1	2	2	2	2	3	0.5	0.25
-9	1	1	1	0	0	0	0.125	0.109375

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.54
n	8
SD50	-8.04
SE	0.25
xp	-6

Cytotoxicity (product)				Product concentration			Neat	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Product supression control				Product concentration			Neat	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	3	3	4	4	2	3	0.79166667	0.164931
-8	2	2	2	1	3	1	0.45833333	0.248264
-9	1	0	0	0	0	0	0.04166667	0.039931

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.29
n	8
SD50	-7.79
SE	0.25
xp	-6

Interference control (untreated)				Product concentration			Neat	
Dilution	Counts						% CPE	p(1-p)
-1	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	1	0
-8	3	3	4	4	4	4	0.91666667	0.076389
-9	2	2	1	1	0	0	0.25	0.1875
-10	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.1667
n	10
SD50	-8.667
SE	0.1712
xp	-7

Raw data

Interference control (treated)					Product concentration			Neat	
Dilution	Counts							% CPE	p(1-p)
-1	4	4	4	4	4	4		1	0
-2	4	4	4	4	4	4		1	0
-3	4	4	4	4	4	4		1	0
-4	4	4	4	4	4	4		1	0
-5	4	4	4	4	4	4		1	0
-6	4	4	4	4	4	4		1	0
-7	4	4	4	4	4	4		1	0
-8	3	3	3	3	3	3		0.75	0.1875
-9	2	2	1	0	0	0		0.20833333	0.164931
-10	0	0	0	0	0	0		0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	1.9583
n	10
SD50	-8.458
SE	0.1979
xp	-7

Test product		Product concentration				Neat	Contact time		1 minute
Dilution	Counts							% CPE	p(1-p)
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	1	1	1	1	2	3	3	0.375	0.234375
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	1.38
n	8
SD50	-3.88
SE	0.18
xp	-3

Test product		Product concentration				50%	Contact time		1 minute
Dilution	Counts							% CPE	p(1-p)
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	2	2	2	2	1	0	0	0.375	0.234375
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	1.38
n	8
SD50	-4.88
SE	0.18
xp	-4

Test product		Product concentration				0.10%	Contact time		1 minute
Dilution	Counts							% CPE	p(1-p)
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	2	2	3	3	3	4	4	0.70833333	0.206597
-8	2	2	2	0	1	4	4	0.45833333	0.248264
-9	1	0	0	0	0	0	0	0.04166667	0.039931

Organism	*Feline Coronavirus* Strain Munich
d	1
sum px	2.21
n	8
SD50	-7.71
SE	0.27
xp	-6

KEY

CPE	Cytopathic effect		
Counts	0-4 indicating degree of cytopathic effect 0 = No effect, 1 = 25% CPE, 2 = 50% CPE, 3 = 75% CPE, 4 = 100% CPE		
d	Dilution factor (log)		
Sum px	Sum of % CPE from the highest dilution showing 100% CPE to the lowest dilution assessed.		
n	Number of dilutions		
SD50	Dilution showing 50% of the end point according to Spearman-Kärber method		
SE	Standard error		
xp	Lowest dilution showing 100% CPE		
TCID50	Titre causing 50% of the end point according to Spearman-Kärber		
PASS	= lg R greater than or equal to 4		
FAIL	= lg R less than 4		
>	greater than	≥	equal to or greater than
<	less than	≤	equal to or less than

Calculation notes

In cases where the highest dilution assessed has not shown 100% CPE, the value has been calculated assuming the dilution above this would give 100% CPE and the corresponding value has been assigned as <x.

The standard requires the product suppression control to show a <0.5 log reduction in viral titre. In cases where the product has failed to achieve the required 4 log reduction, but the product suppression control shows a >0.5 log reduction the result has been deemed as valid for fail as the consequence of inadequate suppression would be a partially extended contact time which would generate false positives, but not false negatives.

A similar approach has been taken in regards to the cytotoxicity controls. The standard requires a 4-log difference between the cytotoxicity level and the viral titre. In cases where this is not obtained, but the log reduction observed by the product is within the difference between the cytotoxicity levels and the viral titre the result is deemed acceptable for a fail as there will be no impact on the determination of efficacy.