

REPORTING COMPLETED BY:



Microchem Laboratory adheres to ASTM E1153 testing methods and meets the following requirements in order to be scientifically defensible:

- Ordinary consistency between replicates must be observed for the control carriers
- Positive/Growth controls must demonstrate growth of appropriate test microorganism
- Negative/Purity controls must demonstrate no growth of test microorganism



Results

The results show material reduction of bacteria, fungi, and viruses after the installation of the CASPR units with NC2I® Technology. The difference between the control samples and the samples exposed to the CASPR shows a significant reduction of pathogens on surfaces independently of the pathogen tested. The following data highlights the percentages of reduction of microorganisms on surfaces, compared to a control which has not been exposed to the CASPR technology.

Individual results on surfaces within the test room showed significant reductions ranging from 91% to over 99.998%. The continuous disinfection from low levels of H_2O_2 were found to exert a significant reduction of the microbial burden compared to the control microorganisms non-exposed to the CASPR NC2I® technology.

Testing results indicate that the CASPR units with NC2I® technology materially reduces or eliminates microorganisms on surfaces in a controlled environment. Results showed Bacteria was reduced over 99.998%, Fungi was reduced over 95%, Methicillin Resistant Staphylococcus (MRSA) was reduced over 99.98%, Influenza A (H1N1) was reduced over 99.93% and MS2 (virus) was reduced over 99.993%, on surfaces during the test period.

The CASPR NC2I® Technology was very effective in eliminating hospital indigenous pathogens, including MRSA, upon contact on all surfaces.

Protocol and Procedures

The test microorganism is prepared, usually by growth in liquid culture medium or on an appropriate agar plate. The test culture may be supplemented with an artificial soil load, such as horse or fetal bovine serum, for one-step cleaner/sanitizer claims. Sterilized carriers are inoculated with a volume of the test culture. Inoculated slides are dried and only completely dried carriers are used in the test. Test carriers are treated with the test device and incubated for the predetermined contact time. Control carriers are harvested at appropriate intervals to accurately represent any reduction during the contact time. At the conclusion of the contact time, test and control carriers are chemically neutralized. Dilutions of the neutralized test substance are evaluated using appropriate growth media to determine the surviving microorganisms at the respective contact time. The effect of the test substance is compared to the effect of the control substance in order to determine microbial reductions.

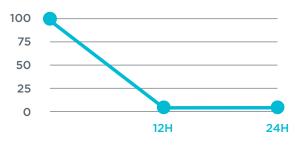


Reduction in Pathogen Levels

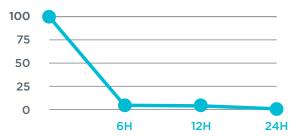
Methicillin Resistant Staphylococcus aureus (MRSA)



Enteroccus faecalis (VRE)



Pseudomonas aeruginosa



Feline Calicivirus



Trichophyton interdigitale



Influenza A (H1N1)



MS2 Bacteriophage (MS2)

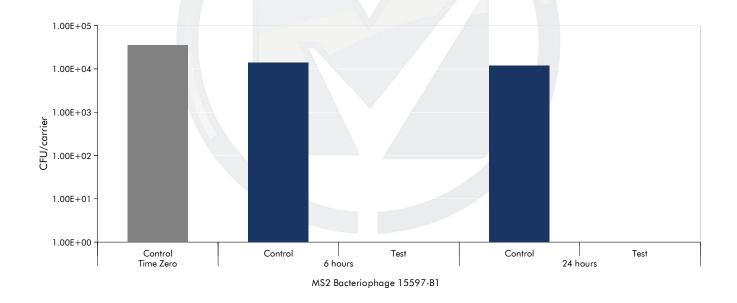




Results of the Study MS2 Bacteriophage ATCC 15597-B1

Test Microorganism	Contact Time	Run Type	CFU/carrier	Percent Reduction vs. Parallel Control	Log ₁₀ Reduction vs. Parallel Control	
	Time Zero	Control	3.50E+04	N	/A	
MS2	6 hours 24 hours	Control	1.40E+04	N/A		
Bacteriophage ATCC 15597-B1		Test	<1.00E+00	>99.993%	>4.15	
		Control	1.19E+04	N/A		
		Test	<1.00E+01	>99.92%	>3.08	

Note: the limit of detection for the 6-hour contact time was 1.00E+00 CFU/carrier and for the 24-hour contact time was 1.00E+01 CFU/carrier. Values observed below the limit of detection are listed as <1.00E+00 or <1.00E+01 in the table and as zero in the graph.



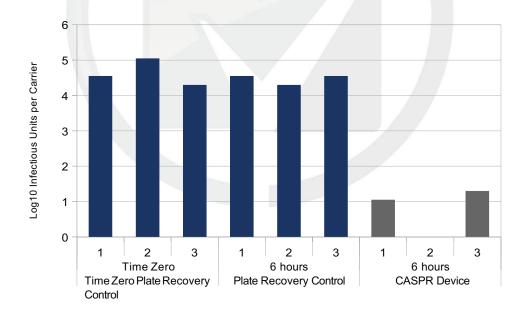


Results of the Study Feline Calicivirus

ATCC - Surrogate for Norovirus

Tes t M icroorganis m	Subs t ance Des ignat ion	Cont act Time	Replicat e	Log I nfect iou s Unit s Per Carrier	Average Log 10 Infect ious Unit s Per Carrier	Average Log 10 Redu ct ion Infectiou s Unit s Per Carrier Compared to Plat e Recovery Cont rol	Average Percent Redu ct ion I nfectiou s Unit s Per Carrier Compared t o Plat e Recovery Cont rol	
			1	4.55				
	Time Zero Plate Recovery Control	Time Zero	2	5.05	4.63	N/A		
			3	4.30				
Feline Calicivirus (EPA-	Plate Recovery Control	6 hours	1	4.55	4.47			
approved human norovirus surrogate),			2	4.30				
ATCC VR-782			3	4.55				
		6 hours	1	1.05	≤1.05	≥3.42		
	CASPR Device		2	≤0.80			≥99.96%	
			3	1.30				

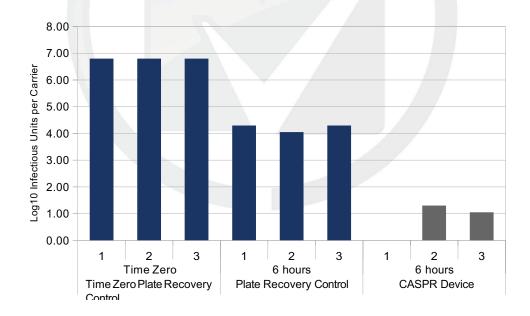
Results for Feline calicivirus, ATCC VR-782:





Results of the Study Influenza A (H1N1) ATTC VR-1469

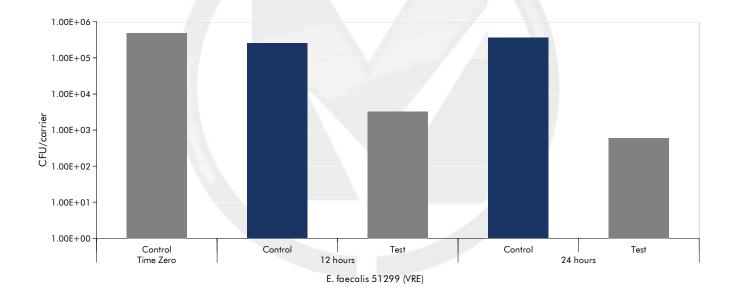
Tes t M icroorganis m	Subs t ance Des ignat ion	Cont act Time	Replicat e	Log I nfect iou s Unit s Per Carrier	Average Log 10 Infect ious Unit s Per Carrier	Average Log Redu ct ion I nfectiou s Unit s Per Carrier Compared t o Plat e Recovery Cont rol	Average Percent Redu ct ion I nfectiou s Unit s Per Carrier Compared t o Plat e Recovery Cont rol	
			1	6.80				
	Time Zero Plate Recovery Control	Time Zero	2	6.80	6.80	· N/A		
			3	6.80				
			1	4.30	4.22			
Influenza A (H1N1), ATCC VR-1469	Plate Recovery Control	6 hours	2	4.05				
			3	4.30				
		6 hours	1	≤0.80	≤1.05	≥3.17	≥99.93%	
	CASPR Device		2	1.30				
			3	1.05				





Results of the Study *E. faecalis* (VRE) ATCC 51299

Test Microorganism	Contact Time	Run Type	CFU/carrier	Percent Reduction vs. Parallel Control	Log ₁₀ Reduction vs. Parallel Control	
	Time Zero	Control	4.90E+05	N	/A	
E. faecalis	12 hours 24 hours	Control	2.60E+05	N/A		
ATCC 51299		Test	3.30E+03	98.73%	1.90	
(VRE)		Control	3.60E+05	N/A		
		Test	6.00E+02	99.83%	2.78	

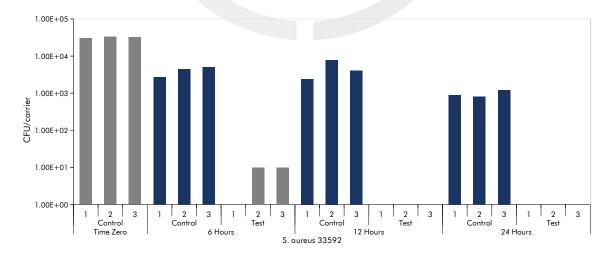




Results of the Study *S. aureus* (MRSA) ATCC 33592

Test Microorganism	Contact Time	Run Type	Replicate	CFU/carrier	Average CFU/carrier	Average Percent Reduction vs. Parallel Control	Average Log ₁₀ Reduction vs. Parallel Control
			1	3.00E+04			
	Time Zero	Control	2	3.30E+04	3.17E+04	N/A	
			3	3.20E+04			
			1	2.70E+03			
		Control	2	4.40E+03	4.03E+03	N/A	
	6 Hours		3	5.00E+03			
		Test	1	<1.00E+01	<1.00E+01	>99.75%	>2.61
			2	1.00E+01			
			3	1.00E+01			
S. aureus	12 Hours	Control	1	2.40E+03		.73E+03 N/A	
(MRSA)			2	7.80E+03	4.73E+03		
ATCC 33592			3	4.00E+03			
		Test	1	<1.00E+00	<1.00E+00	>99.98	>3.68
			2	<1.00E+00			
			3	<1.00E+00			
			1	9.00E+02			
	1	Control	2	8.00E+02	9.67E+02	N	/A
	24 H		3	1.20E+03			
	24 Hours	Test	1	<1.00E+00	<1.00E+00		
			2	<1.00E+00		>99.90%	>2.99
	\		3	<1.00E+00			

Note: the limits of detection for the 6-hour contact time was 1.00E+01 CFU/carrier and for the 12 and 24-hour contact times was 1.00E+00 CFU/carrier. Values observed below the limit of detection are listed as <1.00E+01 and <1.00E+00 in the table and as zero in the graph.

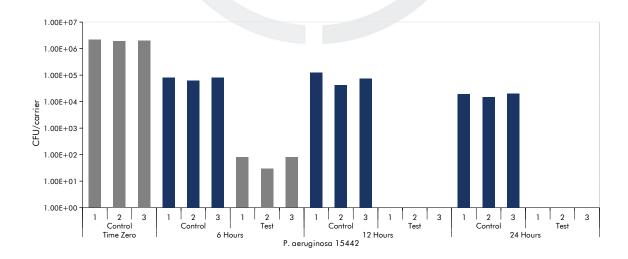




Results of the Study *P. aeruginosa* ATCC 15442

Test Microorganism	Contact Time	Run Type	Replicate	CFU/carrier	Average CFU/carrier	Average Percent Reduction vs. Parallel Control	Average Log ₁₀ Reduction vs. Parallel Control	
			1	2.15E+06	2.04E+06			
	Time Zero	Control	2	1.93E+06		N	/A	
			3	2.03E+06				
			1	7.90E+04				
		Control	2	6.20E+04	7.40E+04	N/A		
	6 Hours		3	8.10E+04				
		Test	1	8.00E+01	6.33E+01	99.91%	3.07	
			2	3.00E+01				
			3	8.00E+01				
	12 Hours	Control	1	1.25E+05		N/A		
P. aeruginosa ATCC 15442			2	4.10E+04	8.00E+04			
AICC 13442			3	7.40E+04				
		Test	1	<1.00E+00	<1.00E+00	>99.998%		
			2	1.00E+00			>4.90	
			3	<1.00E+00				
			1	1.93E+04				
		Control	2	1.51E+04	1.82E+04	N	/A	
	0411		3	2.03E+04				
	24 Hours		1	<1.00E+00				
		Test	2	<1.00E+00	<1.00E+00	>99.995%	>4.26	
			3	<1.00E+00				

Note: the limit of detection for this study was 1.00E+00 CFU/carrier. Values observed below the limit of detection are listed as <1.00E+00 in the table and as zero in the graph

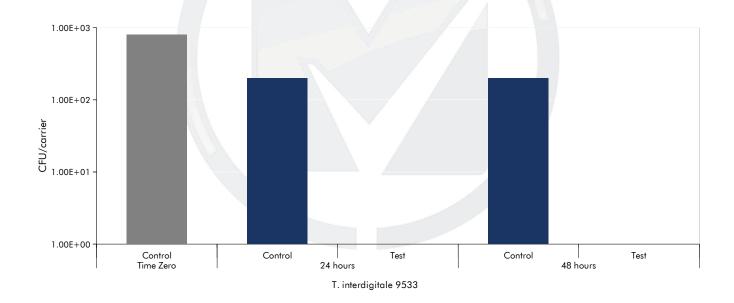




Results of the Study *T. interdigitale* ATCC 9533

Test Microorganism	Contact Time	Run Type	CFU/carrier	Percent Reduction vs. Parallel Control	Log ₁₀ Reduction vs. Parallel Control	
	Time Zero	Control	8.00E+02	N/A		
	24 hours	Control	2.00E+02	N/A		
T. interdigitale ATCC 9533		Test	<1.00E+01	>95.00%	>1.30	
	48 hours	Control	2.00E+02	N/A		
		Test	<1.00E+01	>95.00%	>1.30	

Note: the limit of detection for this study was 1.00E+01 CFU/carrier. Values observed below the limit of detection are listed at <1.00E+01 in the table and as zero in the graph.





GLOSSARY



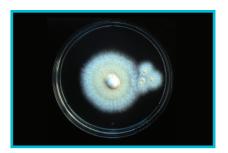
Staphylococcus aureus (MRSA) ATCC 33592

This bacteria is a Gram-positive, cocci shaped, aerobe which is resistant to the penicillin-derivative antibiotic methicillin. MRSA can cause troublesome infections, and their rapid reproduction and resistance to antibiotics makes them more difficult to treat. MRSA bacteria are resistant to drying and can therefore survive on surfaces and fabrics for an extended period of time and therefore makes this bacteria an excellent representative for antimicrobial efficacy testing on surfaces.



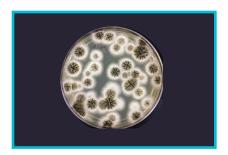
Enterococcus faecalis (VRE) ATCC 51299

This bacteria is a Gram-positive, spherical-shaped strain of Enterococcus faecalis that has developed resistance to the antibiotic vancomycin. E. faecalis (VRE) can cause a variety of local and systemic infections including endocarditis, bacteremia, and urinary tract infections, which are exceptionally difficult to treat because of this strain's acquired drug- resistance. Due to this bacterium's robust survival factors and resistance to commonly used antimicrobial agents, this bacterium is very challenging to disinfect.



Trichophyton interdigitale ATCC 9533

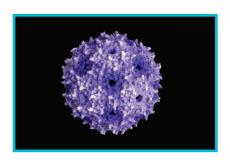
Trichophyton interdigitale is a fungus that is part of a group known as dermatophytes. This fungus is known to cause a skin infection known as Dermatophytosis or Ringworm which appears on a person's skin as an inflamed circular pattern. This fungus produces spores which are difficult to eliminate via disinfection. Disinfection is especially important for environments where Ringworm infections can occur and spread rapidly such as athletic facilities or schools.



Aspergillus brasiliensis ATCC 9642

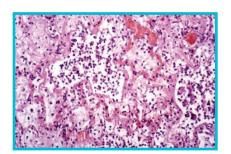
This fungi is a conidiophore, or a sexual spore generating aerobic fungus. A. brasiliensis, formerly listed as a strain of A. niger, is related to other Aspergillus species in that they produce spores which are highly resistant to chemical and environmental conditions. A. brasiliensis is commonly used as a benchmark fungus for antimicrobial fungicides and preservatives used in pharmaceutical and personal care products.





MS2 Bacteriophage (MS2), ATCC 15597-B1

This virus is a non-enveloped positive-stranded RNA virus of the bacteriophage family Leviviridae. Bacterial cells are the hosts for bacteriophages, and E. coli 15597 serves this purpose for MS2 bacteriophage. Its small size, icosohedral structure, and environmental resistance has made MS2 ideal for use as a surrogate virus (particularly in place of picornaviruses such as poliovirus and human norovirus) in water quality and disinfectant studies. Permissive Host Cell System for MS2: Escherichia coli, 15597



Feline calicivirus (FCV), ATCC VR-782

This virus is a non-enveloped, positive-stranded RNA member of the genus Vesivirus, and a common cause of respiratory infections in cats. Symptoms of infection in felines include nasal discharge and mouth ulcers. As a member of the Caliciviridae viral family, FCV is closely related to human noroviruses, which cause acute gastroenteritis marked by nausea, vomiting, and diarrhea. Unlike human norovirus, however, a simple cell culture assay system is available for FCV. Therefore, feline calicivirus is the US EPA-approved surrogate microorganism for human norovirus label claims. Both FCV and human norovirus are able to remain viable on environmental surfaces for extended periods of time and are resistant to a number of disinfectant actives. Permissive Host Cell Line Selected for FCV: CRFK (Crandell-Rees Feline Kidney Cells), ATCC CCL-94



Influenza A (H1N1)

Influenza A virus is an enveloped, minus-stranded member of the family Orthomyxoviridae, and causative agent of the illness influenza (which is more widely recognized by the term 'flu').

Influenza is more serious than other seasonal mild, respiratory tract infections (e.g. the common cold) with symptoms that can last for upwards of several weeks. Young children and the elderly are particularly susceptible to severe illness and death due to infection. Influenza is readily transmitted via infective aerosols direct contact with infective respiratory secretions. Potential transmission by contaminated environmental surfaces (fomites) has increasingly become of interest, and Influenza virus is highly vulnerable to inactivation by drying and exposure to variety of disinfectant actives.

Permissive Host Cell Line Selected for Influenza A (H1N1): MDCK (Madin Darby Canine Kidney Cells), ATCC CCL-34