coVita™
breath analysis is the new blood test

3/16/20

Dear Clients,

At coVita we strive to ensure that we utilize the industry leading infection control technologies and practices. The following information is intended to provide you with specifics about our products in relation to the concerns about the Coronavirus (COVID-19).
Please Note: We recommend that you first follow the protocols and guidelines of your institution/organization as well as local, state and federal health agencies regarding sanitization and infection control best practices, in addition to or in lieu of any information we provide.

Steritouch®: The surface of your monitor(s) (Micro$^{+\ pro}$, ^{baby}, ^{basic}, piCO^{+}™ Smokerlyzers®, Gastro+™, ToxCO®) have an added material known as Steritouch®, an antimicrobial product, offers protection against a range of bacteria including E.coli, MRSA, Salmonella and Legionella, as well as black mold growth, biofilm and fungi[1]. Statement from Steritouch® manufacturer states "Coronavirus COVID-19 is an enveloped virus, so called because of its fatty outer membrane or 'envelope'. Several of the active substances we use have been successfully tested against other enveloped viruses, such as Influenza, Avian flu and SARS. It would be reasonable to imply that those same active substances would be effective against COVID-19, but at this stage testing against COVID-19 is not available[2]."

D-pieces™: The D-piece™ contains an integrated infection control filter with the ability to filter out viral particles and bacterial spores. Against viral particles, the filter in the D-piece™ proved greater than 96% effective at filtering those particles. Against bacterial spores, the filter proved greater than 99% effective at filtering those spores[3]. Of note, the viral particles they choose for these tests are similar in size as the smallest human viruses so that they can test the efficiencies of the filters for removing human viruses from air streams. If you would like a copy of these results, which were conducted by an independent lab, please email us at the email address below for a copy. Although our D-piece™ is cleared to be used on multiple subjects due to the fact that it is a one-way breathing valve, you can dispose of the D-piece™ after individual tests if you have concerns about using the same D-piece™ on a different person. The D-pieces™ have not been tested against COVID-19 specifically, and so we cannot make a claim as to their effectiveness against that specific virus.

SteriBreath™ Mouthpieces: The single use SteriBreath™ mouthpieces are individually wrapped for ease of handling and greater infection control.

GastroCHECK® Mouthpieces: Are specifically designed with integrated filtration to remove: >99% of airborne bacteria, >96% of viruses and any moisture from the patient's breath[3]. Of note, the viral particles they choose for these tests are similar in size as the smallest human viruses so that they can test the efficiencies of the filters for removing human viruses from air streams. The GastroCHECK® mouthpieces have not been tested against COVID-19 specifically, and so we cannot make a claim as to their effectiveness against that specific virus.

Bedfont Wipes: Bedfont recommends the following with regard to their alcohol-free wipes. As standard practice, Bedfont® recommends that the monitors are wiped down with the alcohol-free antibacterial/viral wipes, provided with the monitor, after each breath test. According to the manufacturer, they are effective against the following pathogens (See Table 1). There is no information on their effectiveness specifically against COVID-19.

Foaming Hand Sanitizer: The hand sanitizer provided by coVita is alcohol-free and according to the manufacturer, they are effective against the following pathogens (See Table 2). There is no information on their effectiveness specifically against COVID-19.

Keep in mind the following common-sense precautions and additional information:

- **Do not test ill individuals**: If you know or suspect (based on symptoms) that a person that you would like to offer the breath test to has COVID-19, you should probably avoid the test until they are well. This would generally be advisable for any patients exhibiting cold/flu-like symptoms, not only those with confirmed or suspected COVID-19 infections.
- **Stand off to the side for the test:** You should not stand in front of a person taking the test, as this would place you directly in the stream of air exiting the breath monitor. Stand off to the side as you administer the test regardless of whether you hold the monitor during the test or you let the test subject hold the monitor.
- **Wear gloves and/or sanitize your hands:** You can wear gloves to handle the monitor or if you do not wear gloves, be sure to wash your hands thoroughly or sanitize your hands with approved hand sanitizers when handling the monitor after a breath test. Hand washing/sanitizing would probably be a best practice under most circumstances.
- **Wipe down the monitor:** Do this before (if you do not know whether it was wiped down after the last test) and after each use with an approved sanitizer wipe, but DO NOT SATURATE THE MONITOR WITH EXCESS LIQUID OR ALLOW EXCESS LIQUID TO POOL IN THE SEAMS OF THE MONITOR CASING, AS THIS WILL DAMAGE THE MONITOR AND VOID YOUR WARRANTY.
- **Avoid touching face:** Avoid touching your eyes, nose, and mouth, particularly prior to washing/sanitizing your hands.

Sincerely,

Daniel M. Sibis
Regulatory Affairs

REFERENCES
1. SteriTouch® All you need to know. SteriTouch Ltd. 2018
2. SteriTouch® Website Statement: Coonavirus – The Steritouch Stance. SteriTouch Ltd. 2018
3. Public Health England. An Evaluation of Filtration Efficiencies Against Bacterial and Viral Aerosol Challenges Report No. 17/001. London: Public Health England; 2017.

212 Cottage Grove Ave Suite C Santa Barbara, CA 93101
tel 800.707.5751 ● fax 800.721.2377 ● info@covita.net ● www.covita.net

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(Table 1) Wipe Clinical Efficacy Data

	Standard	Test Organisms	Contact Time
Medical	**EN 16615**	Pseudomonas aeruginosa	5 minutes
Healthcare	**EN 16615**	Staphylococcus aureus	5 minutes
	EN 16615	Enterococcus hirae	5 minutes
	EN 16615	Candida albicans	5 minutes
	EN 13727	E.coli	5 minutes
	EN 13727	Legionella pneumophila	5 minutes
	EN 13727	Listeria monocytogenes	5 minutes
	EN 13727	Pseudomonas aeruginosa	5 minutes
Laboratories	**EN 13727**	Staphylococcus aureus	5 minutes
	EN 13727	Enterococcus hirae	5 minutes
	EN 13727	Vancomycin Resistant Enterococcus (VRE)	5 minutes
	EN 13727	MRSA	5 minutes
	EN 13624	Candida albicans	15 minutes
	EN 14476	Hepatitis C (BVDV)	5 minutes
	EN 14476	Feline Calicavirus (Human Norovirus surrogate)	5 minutes
	EN 14476	Feline Coronavirus	5 minutes

	Standard	Test Organisms	Contact Time
General Purpose	**EN 1276**	E.coli	5 minutes
Hospitality	**EN 1276**	Salmonella enterica	5 minutes
	EN 1276	Klebsiella pneumonia	5 minutes
	EN 1276	Pseudomonas aeruginosa	5 minutes
	EN 1276	Staphylococcus aureus	5 minutes
	EN 1276	Enterococcus hirae	5 minutes
Industry	**EN 1276**	Candida albicans	5 minutes

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(Table 2) ***Foaming Instant Skin Sanitizer Efficacy Data***

In-Vitro Antimicrobial Test Procedures and Protocols:

1. Each test organism was grown overnight on Trypticase-soy agar slants at 35ºC. Cell suspensions were prepared by adding 10mL sterile saline (0.9%) to each slant and gently scraping the slant surface. Microbial densities of each cell suspension were estimated using the viable plate count method.
2. Test product (1mL) was aseptically added to sterile test tubes and then inoculated with a 1:10 dilution of a cell suspension (100 µL) of the test organism. At selected time intervals (0.5, 1.0 and 2.0 minutes), aliquots (10 µL) were aseptically removed and transferred to a Trypticase-soy broth recovery medium (10mL). Microbial growth was monitored by the development of turbidity in the recovery medium.

Test Results:

Foaming Skin Sanitizer with 0.24% Benzalkonium Chloride exhibited strong germicidal activity against a variety of gram-positive and gram-negative bacteria, as well as the yeast Candida albicans. In most instances viable cell numbers were reduced by greater than 99.99% after a 30-second exposure period with this product.

In-vitro Antimicrobial Efficacy for Foaming Skin Sanitizer with 0.24% Benzalkonium Chloride

Organism Type	Test Microorganisms	Initial Inoculum (cfu/10µL)	Exposure Time (Minutes) 0.5 1.0 2.0 Growth in TSB	Reduction (percent)*
Gram Neg -	Pseudomonas aeruginosa	3.39×10^5	- - -	99.99
Gram Neg -	Klebsiella pneumoniae	2.76×10^5	- - -	99.99
Gram Neg -	Escherichia coli	15.8×10^5	- - -	99.99
Gram Neg -	Salmonella typhimurium	18.9×10^5	- - -	99.99
Gram Pos +	Staphylococcus aureus ATTC33591	21.2×10^5	- - - (Methicillin Resistant / MRSA)	99.99
Gram Pos +	Staph. epidermidis	18.3×10^5	- - -	99.99
Gram Pos +	Streptococcus faecalis ATTC522A	9.8×10^5	- - - (Vancomycin resistant entercococci / VRE)	99.99
Gram Pos +	Streptococcus agalactiae	12.1×10^5	- - -	99.99
Gram Pos +	Micrococcus luteus	14.4×10^5	- - -	99.99
Yeast	Candida albicans	12.6×10^5	- - -	99.99
Fungi	Trichophytin mentogrophytes (Athlete's Foot)	9.6×10^5	- - -	99.99
Gram Neg -	Salmonella choleraesuis	14.1×10^5	- - -	99.99
Fungi	Aspergillius niger	11.8×10^5	- - -	99.99
Gram Pos +	Listeria monocytogenes	17.9×10^6	(30 seconds)	0 survival CFU/mL
Gram Pos +	Clostridium difficile	1.1×10^4	(15 seconds)	0 survival CFU/mL

(*) Indicates percentage reduction in numbers of viable cells evidenced by lack of growth in Trypticase-soy Broth medium.

(-) Indicates no survival of test organisms in the recovery medium.

In Vitro Virucidal Tests	Results
Human Coronavirus (resembles SARS-like virus family) (Microbio Test, Inc. – USA)	The product showed virucidal efficacy on all test-viruses.
Influenza virus-A H3N2 (BioScience Labs – USA)	The product showed virucidal efficacy on all test-viruses.

Unless noted, all test performed by Chembac Laboratory – USA

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