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An Introduction to prEN 16777:2016 – Provisional Norm for Virucidal Activity in Surface Disinfectants

The introduction of prEN 16777:2016 heralds a better approach in testing the virucidal activity of surface disinfectants intended for use in the medical area.

Mr. Chin and Ms. Khoo examining cell line

In 2016, the European Committee for Standardization published prEN 16777:2016, a quantitative non-porous surface test for the evaluation of virucidal activity in disinfectants used in the medical area. Also known as phase 2 step 2 carrier test, the provisional test is currently pending approval from CEN members.

Manufacturers and testing laboratories in Europe had been solely relying on EN 14476:2013+A1:2015, a suspension test for the evaluation of virucidal activity in the medical area until the introduction of prEN 16777:2016. The in-vitro method however, is not the best method in validating the effectiveness of surface disinfectants in inactivating viruses. This is because active ingredient molecules and viruses have a better chance of interacting with each other in a suspended state, making the process of inactivating viruses a likely occurence. In reality, viruses are covered in high organic soil such as blood and saliva in medical settings and they adhere to objects and surfaces, preventing them from being inactivated as easily.

For a test to be a valid means of measuring the antimicrobial tendencies of a surface disinfectant, it must be conducted in conditions that resemble real-life situations as closely as possible. This is attainable through phase 2 step 2 carrier tests developed to determine the bactericidal, yeasticidal and fungicidal activities of surface disinfectants. But the tests were never adapted for viruses until 2014 due to an uncertainty in the ability of viruses to withstand the drying process the tests call for.

In a carrier test, the test microorganism suspension is mixed with bovine albumin (for clean conditions) and sheep blood (for dirty conditions) and applied onto a stainless-steel disc known as a carrier. The carrier is left to air-dry to represent actual medical surfaces before the disinfectant is applied for the duration of the recommended contact time. The disc is then submerged into a neutralizer solution to stop the active ingredients from working beyond the contact time. A sample of the neutralizer is acquired, plated

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and incubated. To prove effectiveness, the product must achieve 4 log reduction.

prEN 16777:2016 when ratified, will complement EN 14476:2013+A1:2015 rather than replace it. The virucidal claims of a product must pass EN 14476:2013+A1:2015 test with Poliovirus, Adenovirus and Murine Norovirus and prEN 16777:2016 test with Adenovirus and Murine Norovirus.

The carrier test however, does not include Poliovirus as the virus is not resistant to drying.

At Viroxy, we have a team of experts who conduct tests based on provisional norms to ensure our customers' businesses are not interrupted during the transition period. Are you waiting for the test to be ratified? Don't.

Call us at +60 (0)3 2630 8888 to test your surface disinfectant according to prEN 16777:2016 today!

Viroxy Sdn. Bhd. Affordable · Accredited · Accurate

Founded on 30 June 2016 in the heart of Kuala Lumpur, Malaysia, Viroxy Sdn. Bhd. is a breath of fresh air among testing laboratories providing microbiological and chemical testing services. Apart from disinfectant efficacy testing services which is the mainstay of Viroxy's business, the laboratory also offers sterility testing, bioburden testing, chemical testing and environmental monitoring services and product registration consultancy. With exceptionally short turnaround time and affordable rates, the laboratory has radically changed the course of testing laboratories everywhere.

Viroxy is armed with on-site microbiology, chemistry, tissue culture and virology laboratories fitted with the latest equipment and ready to conduct tests on a collection of 129 microorganisms including bacteria, fungi, viruses and spores. Today, the laboratory is well poised to meet the demands of an impressive line-up of international clients while upholding high-standards embedded within its work culture.

Bearing testament to the capability and resolution of Viroxy's workforce in establishing itself as a formidable player in the field is the laboratory's track record of acquiring ISO/IEC 17025 accreditation with 23 European Norms for disinfectant efficacy testing under the scope within just 16 short months of incorporation, with other standards currently underway.

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