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जैवप्रौद्योगिकी और रोग जीवविज्ञान में आविष्कार, नवीनता एवं अनुवाद की स्वायत्त राष्ट्रीय संस्थान,
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Determination of inhibition of infectious organisms by 365 Tage

Laboratory Medicine and Molecular Diagnostics, Rajiv Gandhi Centre for Biotechnology (RGCB) Bio-Innovation Centre

NABL ISO 15189-2012, NABH & ILAC accredited, Dept of Science and Technology, Govt of India

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Testing Material	365 Tage
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1. Assay Description

1.1 Objective: To evaluate the performance of 365 Tage surface wipe submitted by OshoCorp Global Pvt. Ltd, India

1.2 Purpose: The purpose of this procedure is to evaluate 365 Tage surface wipe. This document applies to the evaluation of surface wipe manufactured by Nation-E innovation GmbH, Berlin and submitted by Osho Corp Global Pvt. Ltd.

1.3 Responsibility: A surface wipe should be able to provide protection from bacteria, virus and other germs contaminating hard surfaces. The wipe should be safe for human and should eliminate infectious organisms within a short period of time.

1.4 Quality Management: The surface wipe was validated at Laboratory Medicine and Molecular Diagnostics (LMMD), Rajiv Gandhi Centre for Biotechnology (RGCB) under quality system procedure of NABL ISO 15189-2012 strictly adhering to ICMR protocols.

2. Experiment Procedure

- The surfaces to be tested was cleaned and disinfected with regular disinfectants that are used
- The surfaces were allowed to air dry at room temperature
- One even coat of 365 Tage surface wipe was applied on each of the test surfaces
- Gaps on coating was analysed using hand-held UV light and the gaps if any, were filled
- The surface sprayed with virus spray amounting to a viral load of 12150000000 for H1N1 virus and 18840000000 for SARS CoV2 virus approximated from the ct value obtained.
- Swabs were collected from the surface at intervals of 1- minute, 2-minute, 3-minute, 4-minute and 5- minute.
- The surface was again disinfected with 5% hypochlorite solution
- This was followed by cleaning with a cationic-based detergent
- The test was repeated to check the adherence of the coating and the effectiveness of the coating subsequent to usage of hypochlorite and detergents.
- The test was performed on 30 different surfaces in triplicate
- Average reading was taken and analysed
- The procedure for bacterial elimination was performed with pure bacterial culture isolates of E-coli, Staphylococcus, and Streptococcus to check the efficiency of the wipe against bacteria

3. Testing Procedure

- The kits used for validation were CE marked and IVD certified kits.
- Kit used for nucleic acid extraction was Qiagen® RNA extraction™ kit.
- SARS CoV 2 real time PCR and H1N1 real time PCR were performed on extracted RNAs using Real Star SARS-CoV-2™ RT-PCR kit 1.0, Real Star Influenza™ screening and type 4.0, Altona Diagnostics® GmbH-Germany, 023005 adhering to manufacturer's instructions.
- The swab taken from the surface for the detection of E-coli, Staphylococcus and Streptococcus after regular timed intervals were resuspended in nutrient broth and

subsequently streaked on to MacConkey agar and enrichment media to test for bacterial growth.

3. Observation

SARS CoV 2 concentration against time		Remaining virus
Time	Log_{10} Factor	
0 Min	0	18840000000
1 Min	1.00	942000000
2 Min	2.00	47100000
3 Min	3.00	1413000
4 Min	4.00	42390
5 Min	5.00	0

H1N1 concentration against time		Remaining virus
Time	Log_{10} Factor	
0 Min	0	12150000000
1Min	1.00	486000000
2 Min	2.00	19440000
3 Min	3.00	583200
4 Min	4.00	11664
5 Min	5.00	0

It was observed that there was a significant log reduction in viral load.

No growth observed on MacConkey agar and enrichment media after 5 minutes of exposure.

The chemical coating is resistant to most of the laboratory grade detergents, disinfectants and sterilizing agents.

4. Disclaimer

1. The protocol being followed is not a live virus assay done using a compatible cell line, as it requires a BSL3 facility.

2. The viral detection protocol has been modified to adapt to the current pandemic situation.

3. The assay determines the loss of viral envelop protein integrity, thereby theoretically inactivating the virus as demonstrated through degradation of E, S, N gene RNA. The test also uses pure bacterial isolates to determine bactericidal activity.

4. The results may be used to further develop the quality of the material used in viral/bacterial studies and for research use.

6. Under no circumstance, the test results can be used as a certificate of compliance as per any ISO standards.

7. RGCB does not endorse any product and the result is given only for material submitted for analysis. Further performance of the products developed rests solely' on the manufacturer and batch to batch consistency maintenance is the responsibility of the manufacture.

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