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MICRO-TEST REPORT

SPONSOR:	Novaerus (Ireland, UK) Ltd./Trivector Biomed LLP(Mumbai,India)
SPONSOR CONTACT:	Kieran McBrien / Dilip Patil
STUDY TITLE:	Evaluation of Inactivation of Airborne *Mycobacterium tuberculosis*
TEST DEVICE:	Novaerus Airborne Infection Control unit NV200
LOT NO./SERIAL No.:	PA1W-230-120
ACTIVE INGREDIENT(S):	Plasma field(Dielectric Barrier Discharge Cold Plasma)
CHALLENGE ORGANISM(S):	Clinical isolate *Mycobacterium tuberculosis* (MTB)
EXPOSURE TIME(S):	15 minutes
CONTACT TEMPERATURE:	19 - 21°C (Ambient)
TEST PERIOD:	45 Days

Checked by

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OVERVIEW OF TESTING CONDITIONS/EXPERIMENTAL DESIGN

The test device NV200, is an air purification unit based on plasma technology alone; i.e. there are no additional technologies packed in the purification device such as filtration media or UV radiation. The NV200 unit dimensions are approximately 28.3 cm (H) x 13.2 cm (W) x 10.8 cm (L). The NV200 air flow is 50 m^3/hr. The NV200 power consumption is 20 W.

The NV200 unit was placed inside plastic enclosure (52 x 41 x 32 cm^3); test enclosure volume is approximately 68 litres. The plastic enclosure and test set up was placed inside a Bio-Safety Cabinet (BSC). The fan within the BSC was always kept *OFF* during test runs.

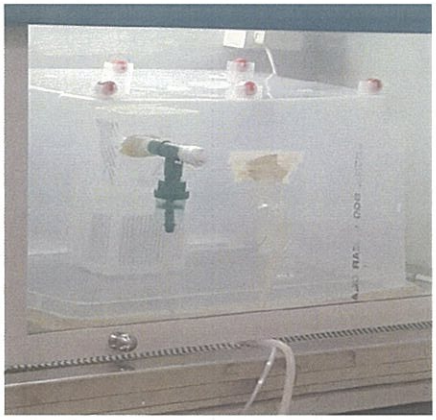

Figure 1: Test set up, NV200 unit inside test enclosure; all placed inside the BSC. Nebulizer and SKC BioSampler attached to test enclosure.

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Clinical isolate of *Mycobacterium tuberculosis* was aseptically transferred into sterile MGIT tube and Lowenstein Jenson (LJ) medium. This was incubated at 37°C for approximately 42 days. The growth on LJ medium was transferred to container containing Sterile glass beads. The MGIT bottle with growth was matched to 1 McFarland Standard No. (containing 3×10^8 CFU/ml cell density).

One millilitre (1 ml) of sterile MGIT medium was used to capture the air within the enclosure prior to the exposure to bacterial suspension using a SKC bio-sampler. This sample serves as a negative control. One millilitre (1 ml) of the Bacterial suspension was transferred to the CompAir Pro nebuliser to aerosolise *M. tuberculosis* cells. A sterile SKC BioSampler containing 1 ml of sterile MGIT medium was placed at the output of the enclosure to capture the aerosolised bacteria during the test cycle. The testing system was automated. The bacterial solution was fed into the test enclosure for 5 minutes, followed by NV200 processing time of 15 minutes. The SKC BioSampler then runs for 5 minutes to collect any microorganism present within the test environment. The SKC BioSampler was removed and inoculated on to the appropriate media. (LJ and MGIT tubes).

The positive and negative control samples were carried out in the very same way with the exception of the NV200 being turned *OFF* for the duration of the control test cycle.

The MGIT tubes were incubated as per manufacturer's instructions (BD MGIT 320) and LJ media are incubated for 45 days at 37°C. Following incubation, the tubes are monitored for growth. The reduction is then calculated by comparing the controls to the test MGIT tubes and LJ media.

The BSC fan was turned *ON* after every test cycle to clear the test environment and the test chamber was decontaminated with a disinfectant spray to ensure there was no microorganisms present in the environment before the next test cycle. The nebuliser was immersed in 2% Glutaraldehyde solution for 1 hour and was discarded according to BMW guidelines 2016. The SKC BioSampler was also treated similarly and cleaned and autoclaved.

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RESULTS

It was observed that positive control MGIT tube showed growth in 5 days whereas LJ medium showed growth in 15 days.

There was no growth in the negative control MGIT and LJ medium even after 45 days of incubation at 37°C.

There was no growth in the test MGIT and LJ medium after 45 days of incubation at 37°C.

Figure 2: Positive control in LJ medium (left) and Test in LJ medium after 45-day incubation at 37°C (right)

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CONCLUSIONS

No growth of Mycobacterium Tuberculosis cells is observed in the air sample collected from the test enclosure post-exposure to the NV200 unit. This shows that the device has effectively rendered all airborne *Mycobacterium Tuberculosis* non-viable.

Dr. Roopa Viswanathan Iyer, MD DNBE DHA
Study Director

Date: 10th December 2016

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