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Test report

Lille, 13th November, 2017

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Azelies

Test report N. 170187
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DEVICE: Novaerus Airborne Infection Control Unit Model NV200
Serial number: PA1W2301203502/1700056
Device received on 26th October, 2017
Tests conducted from 9th November, 2017 to 13th November, 2017

TEST: Validation of the efficiency of an air purifier for removal of Influenza virus H1N1

These results concern only the tested device.

This report has 5 pages

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I- Context

NOVAERUS developed an air purifier inactivating particles from air thanks to a plasma field. Biological air contaminants include viruses such as Influenza virus H1N1. This virus is responsible for flu in infected persons. It is transmitted via inhalation of contaminated droplets emitted by sick people through sneezing or coughing.
The aim of the test is to evaluate the ability of the air purifier to remove H1N1 virus from the air. In an air tight environment, contaminated droplets containing the virus will be aerosolized. The air purifier will then be started to 'cleanse' the air. After a determined operation time, air will be sampled and analysed for quantitation of the remaining virus population.
Efficiency of the purifier will be evaluated based on the log reduction of the viral count in air.

II- Materials and methods

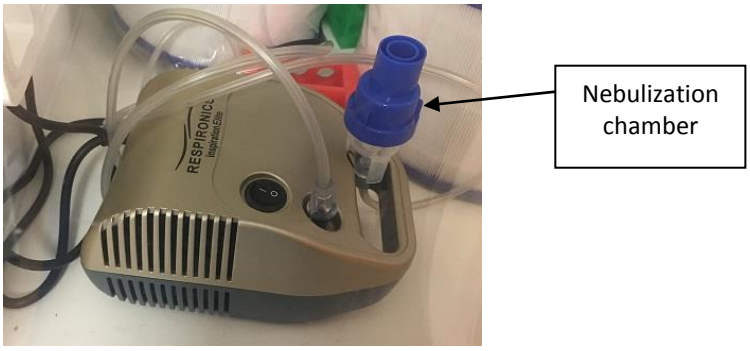
1. Strains and media

The study was conducted on Influenza virus H1N1 A/PR/8/34 (ATCC 1469). The virus was produced and titrated on cell line MDCK (ATCC CCL-34). Cells were grown in Minimal Essential Medium (MEM) supplemented with 10% Fetal Calf Serum.
Viral titres were determined using the Spearman-Kärber method, as recommended by European Standard NF EN 14476+A1 (October 2015), and expressed in 50% Tissue culture Infective Dose ($TCID_{50}$).

Liquid medium used for nebulization was Phosphate Buffer Saline (PBS). Air samples were collected in PBS + 0.005% Tween 20.

2. Material

A medical nebuliser (Respironics, Philips) was used to generate aerosols. This device is used for administration of inhalable medicine, thus ensuring that the generated droplets are in the inhalable fraction representative of particles at risk. A nebulization chamber is connected to the system.



Air sampling was performed using the Coriolis µ (Bertin Technologies), which collects samples by impinging in a cyclone formed by the collecting fluid in a conic flask. Sampling is performed at 300 litres/minute.

The air purifier operates at an air flow of 50 m^3/hour.

Experiments were performed inside a biological safety cabinet, safety level 3. The inner volume was 537 litres (or 0.537 m^3). Air renewal was switched off during the tests, to prevent aerosols from getting trapped in the cabinet filters.

3. Experimental design

Only two conditions were tested: purifier switched off during the test, or purifier switched on. Each was conducted 3 times, amounting to 3 x 2 = 6 tests.

Running time has been defined according to the air flow voloume of the purifier and the inner volume of the cabinet. The air flow is 50,000 L/hr, corresponding to 13.9 L/sec. Given the volume of 537 L of the safety cabinet, **a running time of 39 seconds corresponds to a single passage** of the air inside the cabinet through the purifier. 5 seconds were added to account for the activation time of the plasma. The final operation time of the purifier was then **44 seconds**.

4. Experimental setup

A highly concentrated suspension of H1N1 virus was prepared for each experimental series. 1 mL of the virus suspension was mixed with 7 mL PBS and placed inside the nebulization chamber. 100 µL were removed for viral enumeration before the start of the experiment.

Collection flasks were filled with 15 mL of PBS + Tween 20.

For each experiment, the nebulizer was switched on for 5 minutes. Then, simultaneously, the nebulizer was switched off and the purifier was either switched on or left off. After a defined time, the purifier was switched off (or left off) and, simultaneously, the air sampler was switched on for 5 minutes. At the end of the sampling time, the collection flask was removed and closed.

Three successive tests were conducted in the same conditions (either purifier on or purifier off), using the same nebulizing solution, but with a different collection flask each time. At the end of these 3 tests, the nebulization chamber was removed; the remaining volume was measured and the viral population was enumerated again. Collection flasks were analysed after a concentration step, allowing to lowering the detection limit of the collected viral load.

At the end of an experimental day, the safety cabinet was decontaminated by nebulizing a disinfectant (peracetic acid + hydrogen peroxide). The cabinet was aerated before new tests were performed.

5. Data analysis

The following values are measured during the test:

-	Viral concentration in nebulizing solution	Cn	(in $TCID_{50}$/mL)
-	Initial volume of nebulizing solution	Vni	(in mL)
-	Final volume of nebulizing solution	Vnf	(in mL)
-	Viral concentration in concentrated collection solution	Cc	(in $TCID_{50}$/mL)
-	Volume of concentrated collection solution	Vc	(in mL)

The former values are used to calculate the following values:

-	Nebulized volume	Vn = Vni – Vnf	(in mL)
-	Nebulized quantity of virus	Qn = Cn x Vn	(in $TCID_{50}$)
-	Collected quantity of virus	Qc = Cc x Vc	(in $TCID_{50}$)
-	Viral reduction during the experiment	R = Log(Qn) – Log (Qc)	(in Log($TCID_{50}$))

Finally, the impact of the purifier is evaluated by comparing values of R with the purifier on (R_{on}) to values obtained with the purifier off (R_{off}), for identical running times. The log reduction observed in experiments with the purifier switched on is supposed to be caused by several sources:

- Impact of the purifier,
- Impact of the experimental conditions (nebulization stress, impact on surfaces, sedimentation…).

It is assumed that the second source of viral loss is identical whether the purifier is switched on or off. Therefore, it is estimated by experiments where the purifier is switched off (R_{off}).
The value of interest, defined as the removal ability of the purifier alone R_P, is eventually evaluated as

$$R_P = R_{on} - R_{off}$$

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III- Results

Results are presented below.

Purifier	Nebulized quantity Qn ($TCID_{50}$)	Collected quantity Qc ($TCID_{50}$)	Viral reduction R	Average R	Log reduction caused by purifier R_P	% removal caused by purifier
Off	7.3×10^{7}	4.2×10^{4}	3.2	3.9		
		5.6×10^{3}	4.1			
		4.2×10^{3}	4.2			
On	7.0×10^{7}	7.5×10^{3}	4.0	4.2	0.3	51.8%
		3.2×10^{3}	4.3			
		4.2×10^{3}	4.2			

Log reductions caused by the purifier (R_P values in Table) are estimated by subtracting the log reduction of virus observed in the experiments conducted with the purifier switched off from the log reduction of virus observed in the experiments conducted with the purifier switched on, for the same running time.

IV- Conclusion

The Novaerus Airborne Infection Control Unit Model NV200 was able to remove **51.8% of Influenza H1N1 virus from air after 1 passage** through the purifier.

End of test report