

## NHS Biovalidation of Rensair Air Purifiers



### Executive Summary

In November 2022, the NHS Innovation Agency, based in Liverpool, United Kingdom, completed testing of the Rensair Core (Q01B) air purification device to validate the bio-efficacy of the device using the “Liverpool Biovalidation Protocol”.

The test was completed in a 129.7m<sup>3</sup> room. The results confirm that the Rensair Core achieves a 90% reduction (log-1 reduction) in airborne pathogens per cubic metre of air in only 11.4 seconds. That equates to a 99.9% reduction (log-3 reduction) in 34.2 seconds.

Additionally, the results provided a pathogen Clean Air Delivery Rate (CADR) of 655m<sup>3</sup> per hour for the device. These findings are consistent with prior independent tests performed on the Rensair Core device by Eurofins and the Danish Technological Institute (DTI) and the CFD studies undertaken by the ESI Group in an NHS Birmingham dental suite.

The NHS test results and its supporting data allow Infection Prevention & Control (IPC) professionals to confidently utilise Rensair air purification devices to mitigate airborne disease transmission risk in poorly ventilated areas, including hospital wards and areas where Aerosol Generating Procedures (AGPs) are performed.

### Background

Rensair technology has been used in the healthcare sector for over two decades. An extensive library of independent documentation validating the effectiveness of the Rensair devices has been built up during this period - the documentation can be [found here](#).

Rensair began supplying the NHS with air purification solutions in 2020. Today more than 50 NHS hospitals, as well as numerous primary care clinics, doctors and dental surgeries, rely on Rensair air purifiers to reduce the risk of airborne disease transmission.

Many air cleaning devices appeared on the market during the pandemic, with widely different technologies and aggressive marketing claims. To allow IPC professionals to make informed decisions, the NHS decided to establish a single uniform test protocol to confirm an air purifier’s bio-efficacy, which resulted in the Liverpool Biovalidation Protocol.

NHS Supply Chain has adopted this protocol as part of their criteria for accepting companies on their procurement portal. Additionally, the protocol is expected to contribute to new standards designed by the British Standards Institute (BSI) and subsequently standards drawn up by the International Organisation for Standardisation (ISO).

## The Liverpool Biovalidation Protocol

The NHS England Chief Scientific Officer commissioned the Innovation Agency to develop the protocol. The Innovation Agency is part of NHS England and the Office for Life Sciences, a British Government department. More information regarding the Innovation Agency's air purifier testing work can be [found here](#).

The protocol was developed by Professor Anthony C. Fisher and Dr. Nicholas P. Rhodes. Professor Fisher is a Consultant Clinical Scientist at the Royal Liverpool University Hospital and Head of the Department of Medical Physics & Clinical Engineering at the University of Liverpool. Dr Rhodes is a Reader in Tissue Engineering and Regenerative Medicine at the University of Liverpool.

The protocol, which is attached to this document, uses *Micrococcus Luteus* as the test pathogen, which is suspended into aerosols using a nebuliser. *Micrococcus Luteus* is considered a robust bacteria with low UVC susceptibility, meaning that it is among the hardest strains to inactivate with UVC light. Therefore, removing other airborne virus or bacteria strains should yield similar or better test results compared to the protocol test.

The test on the air purification device was performed five times. The air was sampled at least every 10 minutes each time. Additionally, five tests were performed without operating the air purification device in order to establish the natural decay rate of the airborne pathogens. The tests were also compared to a control sample of data using a Midtherm 500 UVC device, where the removal rate is well understood, thereby allowing for the normalisation of results to account for differences in different batches of bacteria colonies.

The tests were carried out in a 129.7m<sup>3</sup> (4,580ft<sup>3</sup>) laboratory with controlled temperature and humidity conditions at the Royal Liverpool University Hospital, United Kingdom.

## Rensair Core Test Results

The test results evidence that the Rensair Core achieves a 90% reduction (log-1 reduction) in airborne pathogens per cubic metre of air in 11.4 seconds. As a reference, the Control product (the Midtherm 500 UVC device, a product also used by the NHS) required 25.9 seconds to achieve the same reduction. Rensair therefore performed 2.3 times better than the Control product, despite both products having similar air flow rates.

The pathogen Clean Air Delivery Rate (CADR) of the Rensair Core was also calculated to be 655m<sup>3</sup> per hour.

The test data showed that the Rensair device achieved a 99.6% reduction (log-2.4 reduction) in the 129.7m<sup>3</sup> room after 60 minutes of operation. In a typical consultation room of 40m<sup>3</sup>, calculations show that a 90% reduction (log-1 reduction) in airborne pathogens can be achieved in 8.4 minutes and a 99% reduction (log-2 reduction) can be achieved in 16.9 minutes.

## **Conclusion**

The test data generated in accordance with the Liverpool Biovalidation Protocol show that the Rensair Core device removes airborne pathogens effectively. Based on tests carried out in a 129.7m<sup>3</sup> room, the Rensair Core achieves a 90% reduction (log-1 reduction) in airborne pathogens per cubic metre of air in only 11.4 seconds. The results provided a pathogen Clean Air Delivery Rate (CADR) of 655m<sup>3</sup> per hour for the Rensair Core device.

These findings are consistent with prior independent tests performed on the Rensair Core device by Eurofins and the Danish Technological Institute (DTI) and the CFD studies undertaken by the ESI Group in an NHS Birmingham dental suite.

# **Biovalidation Protocol**

## **(High efficiency standalone version)**

for the real-world evaluation of air purifiers

Professor Anthony C Fisher  
Dr Nicholas P Rhodes  
**9.11.2022**

# Biovalidation Protocol

High Efficiency Standalone Version 1.00, 9.11.2022

## Materials

- *Micrococcus Luteus*, Strain ATCC10240 or equivalent as a lyophilised powder;
- Maximum recovery diluent (MRD): 8.5 g NaCl and 1 g peptone in 1 litre of water, pH:  $7.0 \pm 0.2$ , as described in ISO 6887: BS5763;
- Nutrient broth: general, non-selective;
- Non-selective agar plates: 90 mm diameter, supplemented with yeast extract;
- Tryptone soya agar (TSA) plates: 90 mm diameter;

## Equipment

- Inoculation loops;
- Refrigerator set to 2-7°C;
- Heater: Capable of heating, or cooling, if appropriate, the selected chamber to 23°C;
- Humidifier: Capable of humidifying the selected chamber to 50%, or dehumidifying, if appropriate;
- Nebuliser: allowing aerosolization of bacterial suspension at approximately 0.5-2 mL/min with aerosols having a mean aerodynamic diameter of 1-3  $\mu\text{m}$ ;
- Air sampler: capable of sampling into a fluid that maintains bacterial viability at a rate of up to 300 L/min.
- Antimicrobial fogger: capable of disinfection of surfaces and air commensurate with the chamber volume.

## Protocols

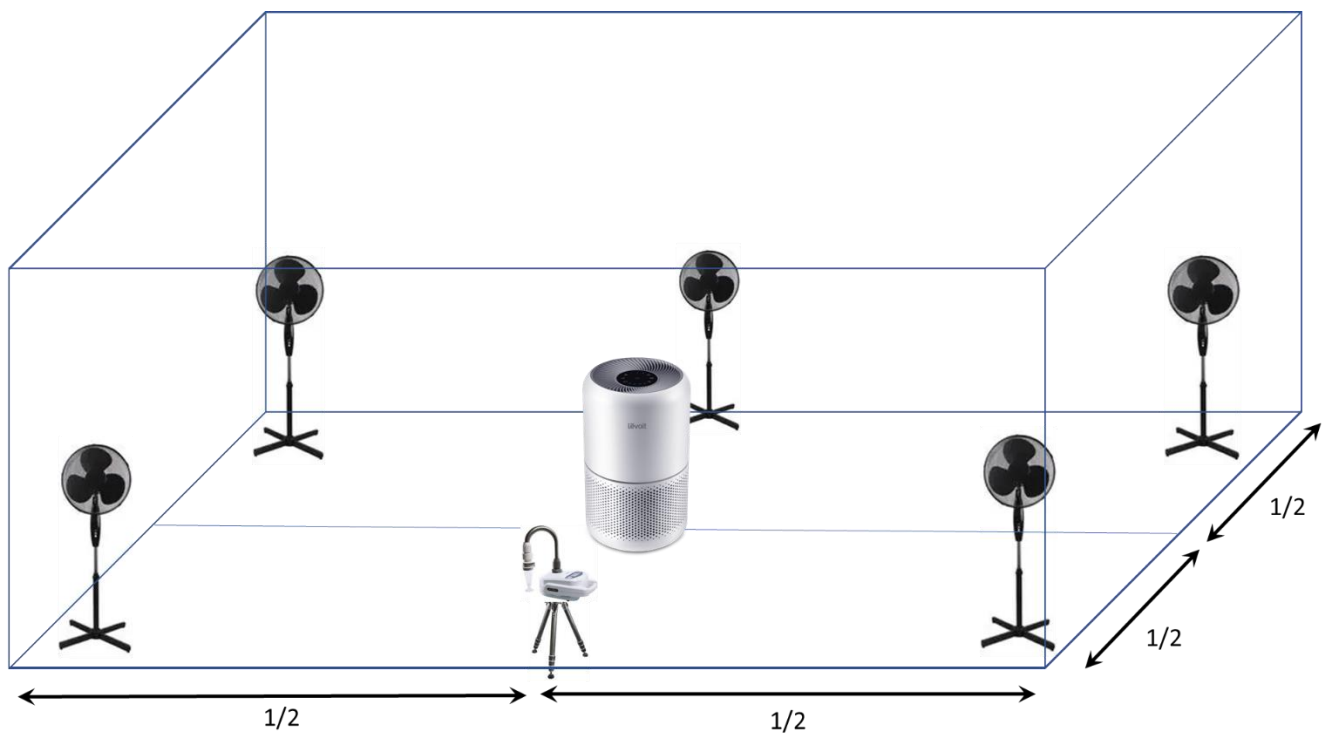
### 1. Cell Culture

- 1-1 The lyophilised bacteria should be resuscitated by reconstituting in 0.5 mL MRD or nutrient broth prior to plating directly onto multiple agar plates (up to 100  $\mu\text{L}$  to each plate) supplemented with yeast extract and streaked across each plate in multiple straight streaks in four directions at an angle of approximately 120° from each other using a sterile inoculation loop.
- 1-2 The plates should be incubated at 30°C for 2-3 days until visible, orange colonies have emerged.
- 1-3 Only bacteria at P1 or P2 from the initial resuscitated culture should be used for biovalidation experiments, for consistency.
- 1-4 Growing colonies are removed using an inoculation loop directly into bottles of 9 mL MRD by smearing onto the bottle wall, in sufficient quantities to achieve a concentration of  $10^9$  cells/mL. The suspension is vortex mixed to ensure aggregates are not present. The bacterial concentration should be determined by either plating through 5 log decades of cell concentration, the use of a Neubauer haemocytometer chamber, or by turbidity measurements.

### 2. Chamber setup

- 2-1 No ISO standard exists for medium to large volume air purifier testing, but where appropriate, the relevant aspects of ISO 16000 part 36 have been used (BS ISO 16000-36:2018).
- 2-2 A rectangular chamber in the range 100-150  $\text{m}^3$  should be equilibrated to a temperature of  $23.5 \pm 0.5^\circ$ , humidity of  $50\% \pm 2\%$  with the interior air mixed at high speed using five oscillating fans of at least 30 cm diameter, four at each corner of the chamber, mounted 1 metre from the floor, and one half-way along the longest dimension.
- 2-3 The walls, ceiling and floor, constructed from a material able to be washed down, should be cleaned to prevent environmental microorganisms affecting bioevaluation.
- 2-4 Nebulisation should be conducted directly in front of one of the fans.
- 2-5 Air sampling should take place half-way along the longest dimension of the room opposite from the fifth fan (illustrated in Figure 1), mid-way between floor and ceiling.
- 2-6 Continuous temperature and humidity monitoring should be conducted at multiple locations around the chamber (a minimum of 4) and additional heating, cooling, humidification or dehumidification performed to maintain appropriate environmental conditions.

- 2-7 The air purification device should be placed on the floor mid-way along the both dimensions of the room with the air blown along the longest dimension, ensuring that the output of the air purifier is not directed toward the air sampler input orifice.



**Figure 1 Environmental chamber arrangement**

### **3. Chamber seeding and air sampling**

- 3-1 Prior to seeding of the chamber, a bacterial suspension of *Micrococcus Luteus* should be prepared, as described in step 1-4. The bacteria should be maintained in MRD at 2-7°C to ensure maximum viability prior to experimentation.
- 3-2 A volume of bacterial suspension for a final chamber concentration of up to  $1 \times 10^8/\text{m}^3$  should be added to the nebuliser and the suspension fully aerosolized, subsequently allowing the room to equilibrate for approximately 10 minutes, or the time period defined in step 3-3.
- 3-3 Baseline characterisation of the room should be conducted by sampling the air at least every 5 minutes for one hour prior to testing of the air purifier, ensuring that air temperature and humidity are maintained at the equilibrium level. An appropriate volume of air should be sampled (recommended approximately 200 L) such that a sufficient volume is sampled allowing several log decades of reduction in bacterial numbers to be measured while removing an insignificant proportion of the total.
- 3-4 Air sampling should be conducted into a fluid able to maintain the viability of the bacteria and prevent additional cell replication, such as MRD, into a volume of approximately 10 mL.
- 3-5 Air should be sampled from the room after switching on the air purifier at least every 10 minutes over a period of an hour.
- 3-6 The sampled bacteria should be maintained at 2-7°C until plated to ensure viability is retained.
- 3-7 The room should be comprehensively disinfected after sampling.

### **4. Enumeration of bacteria and evaluation of air purifiers**

- 4-1 Each MRD sample should be plated out in duplicate onto TSA plates either through a series of 4 or 5 1:10 serial dilutions, or using a plating application that has at least a  $10^4$  dynamic range, such as a spiral plater.
- 4-2 The base 10-logarithm of full room equivalent values of the bacteria should be plotted against time. The baseline characteristics of bacterial loss, as assessed in step 3-3, should be first subtracted.
- 4-3 The rate of air expulsion from the air purifier should be evaluated.
- 4-4 The performance of the air purifier is calculated from the derived decay curve in terms of  $\log_{10} / \text{m}^3 / \text{min}$  or the number of seconds required to reduce the bacteria in  $1 \text{ m}^3$  by  $1 \times \log_{10}$ .

# Validation of the Rensair Q01B Air Scrubber to the Liverpool Biovalidation Protocol



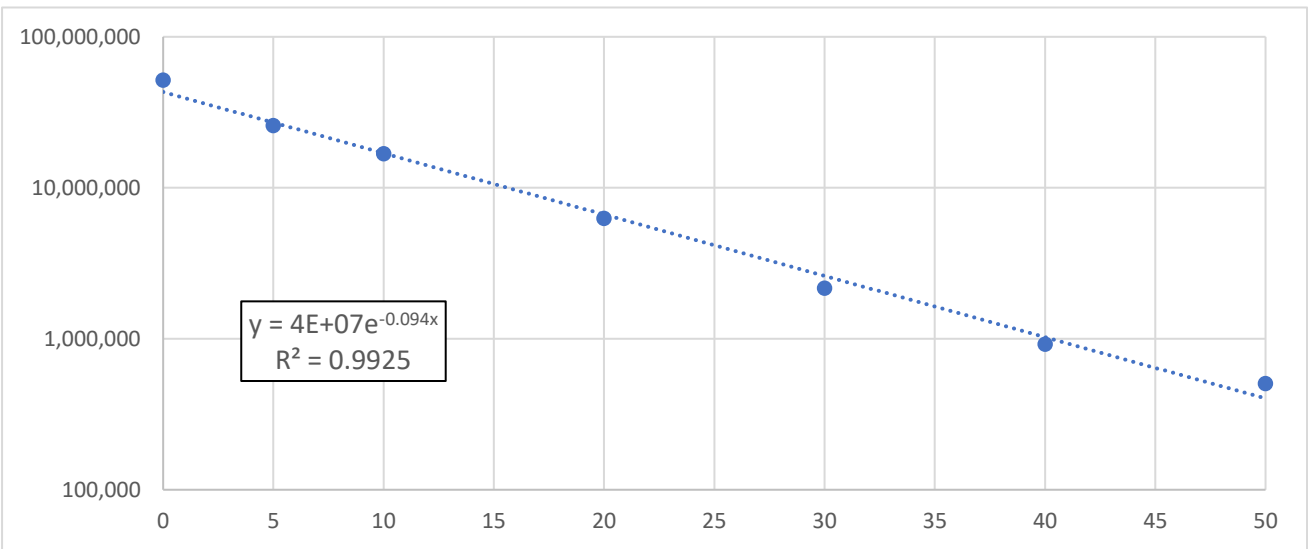
INNOVATION AGENCY

## Rensair Q01B

Ref AS0011  
 Room Chamber 3 used for real-world evaluation  
 Room size 129.7 m<sup>3</sup>  
 Mean Temp 23.4 °C  
 Mean RH 53.3 %  
 Fan Setting 560 m<sup>3</sup>/hr

28/09/2022

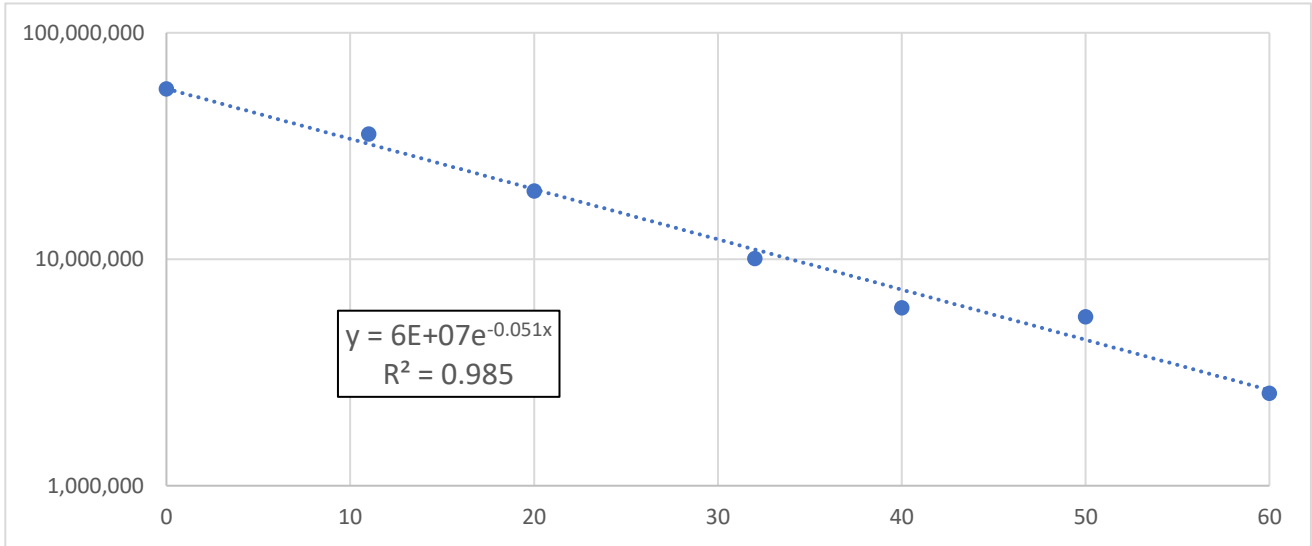
n = 1	Plate Count 1	Plate Count 2	Time (mins)	Room Count		1 hour trend
	8.52E+04	7.41E+04	0	51,653,025	<b>Exponent</b>	-0.094
3.80E+04	4.16E+04	5	25,810,300	<b>Intercept</b>	4.00E+07	
2.27E+04	2.92E+04	10	16,828,575	<b>Calculated 60' count</b>	1.42E+05	
1.01E+04	9.19E+03	20	6,254,783	<b>Log<sub>10</sub> Reduction</b>	2.45	
3.30E+03	3.36E+03	30	2,159,505	<b>minus room</b>	0.264	
1.36E+03	1.48E+03	40	920,870	<b>NET Log<sub>10</sub> Reduction</b>	2.19	
6.80E+02	8.80E+02	50	505,830			



# Control (Midtherm 500)

Plate Count 1	Plate Count 2	Time (mins)	Room Count
7.78E+04	9.63E+04	0	56,451,925
5.77E+04	5.26E+04	11	35,764,775
2.99E+04	3.18E+04	20	20,006,225
1.86E+04	1.25E+04	32	10,084,175
9.60E+03	9.19E+03	40	6,092,658
7.33E+03	9.85E+03	50	5,570,615
4.08E+03	3.80E+03	60	2,555,090

	1 hour trend
Exponent	-0.051
Intercept	6.00E+07
Calculated 60' count	2.81E+06
Log <sub>10</sub> Reduction	1.33
minus room	0.264
NET Log <sub>10</sub> Reduction	1.06

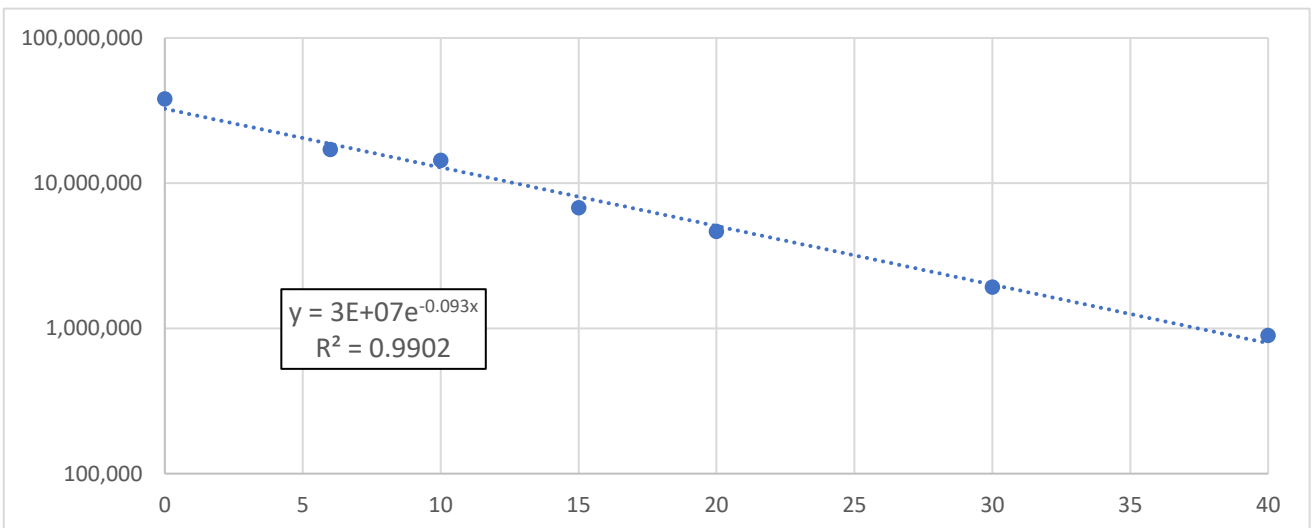


04/10/2022

n = 2

Plate Count 1	Plate Count 2	Time (mins)	Room Count
5.99E+04	6.30E+04	0	38,038,947
2.42E+04	2.84E+04	6	17,055,550
2.27E+04	2.16E+04	10	14,364,275
1.21E+04	1.23E+04	15	6,781,457
8.32E+03	6.00E+03	20	4,643,260
2.78E+03	3.16E+03	30	1,926,045
1.46E+03	1.30E+03	40	894,930

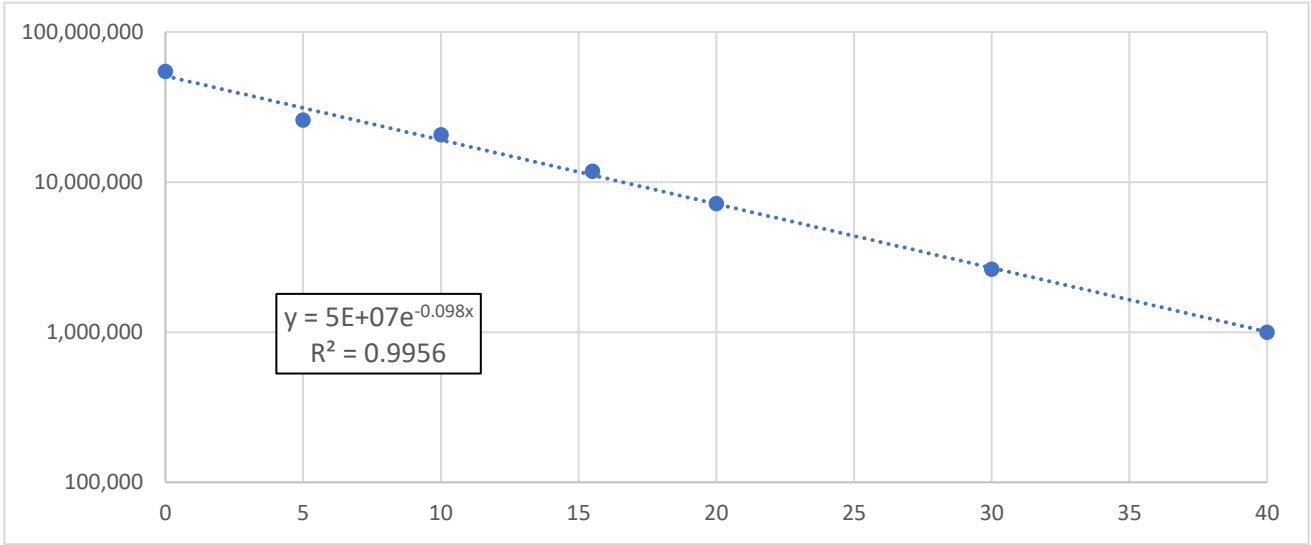
	1 hour trend
Exponent	-0.093
Intercept	3.00E+07
Calculated 60' count	1.13E+05
Log <sub>10</sub> Reduction	2.42
minus room	0.264
NET Log <sub>10</sub> Reduction	2.16



n = 3

Plate Count 1	Plate Count 2	Time (mins)	Room Count
1.02E+05	6.64E+04	0	54,603,700
4.09E+04	3.87E+04	5	25,810,300
2.88E+04	3.50E+04	10	20,687,150
1.97E+04	1.67E+04	15.5	11,802,700
9.85E+03	1.23E+04	20	7,182,138
4.67E+03	3.44E+03	30	2,629,668
1.52E+03	1.56E+03	40	998,690

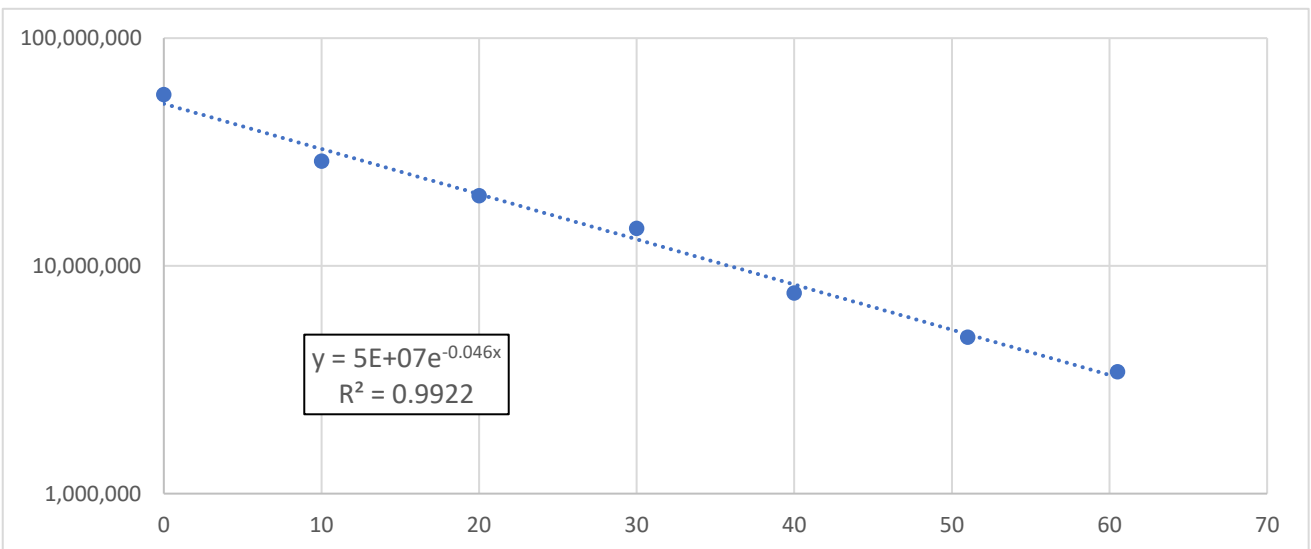
Exponent	-0.098
Intercept	5.00E+07
Calculated 60' count	1.40E+05
Log <sub>10</sub> Reduction	2.55
minus room	0.264
NET Log <sub>10</sub> Reduction	2.29



Control  
(Midtherm 500)

Plate Count 1	Plate Count 2	Time (mins)	Room Count
7.78E+04	9.63E+04	0	56,451,925
4.45E+04	4.45E+04	10	28,858,250
3.50E+04	2.77E+04	20	20,330,475
2.27E+04	2.23E+04	30	14,591,250
1.09E+04	1.25E+04	40	7,587,450
7.33E+03	7.66E+03	51	4,860,508
6.27E+03	4.80E+03	60.5	3,426,291

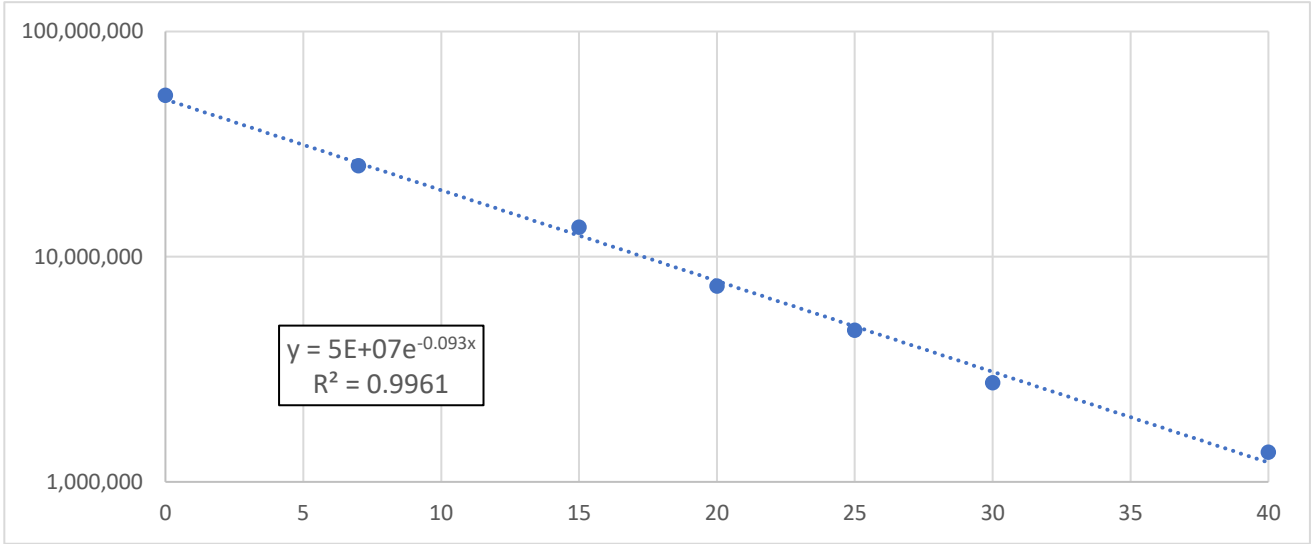
Exponent	-0.046
Intercept	5.00E+07
Calculated 60' count	3.16E+06
Log <sub>10</sub> Reduction	1.20
minus room	0.264
NET Log <sub>10</sub> Reduction	0.93



n = 4

Plate Count 1	Plate Count 2	Time (mins)	Room Count
8.89E+04	7.15E+04	0	52,009,700
4.16E+04	3.65E+04	7	25,323,925
1.97E+04	2.20E+04	15	13,521,225
1.25E+04	1.03E+04	20	7,392,900
7.88E+03	6.67E+03	25	4,717,838
4.67E+03	3.84E+03	30	2,759,368
2.10E+03	2.28E+03	40	1,355,660

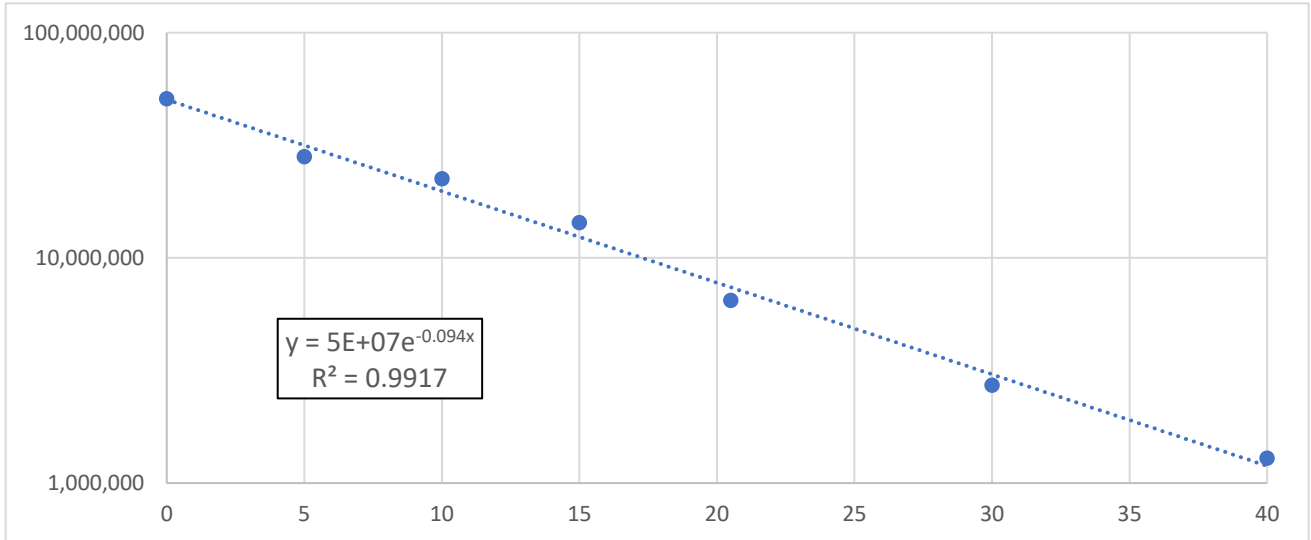
Exponent	-0.093
Intercept	5.00E+07
Calculated 60' count	1.89E+05
Log <sub>10</sub> Reduction	2.42
minus room	0.264
NET Log <sub>10</sub> Reduction	2.16



n = 5

Plate Count 1	Plate Count 2	Time (mins)	Room Count
6.79E+04	8.89E+04	0	50,842,400
4.74E+04	3.94E+04	5	28,144,900
4.16E+04	2.77E+04	10	22,470,525
2.01E+04	2.41E+04	15	14,331,850
9.85E+03	1.01E+04	20.5	6,468,788
4.16E+03	4.24E+03	30	2,723,700
2.22E+03	1.76E+03	40	1,290,515

Exponent	-0.094
Intercept	5.00E+07
Calculated 60' count	1.78E+05
Log <sub>10</sub> Reduction	2.45
minus room	0.264
NET Log <sub>10</sub> Reduction	2.19



## Results summary (bacterial inactivation curve)

$\log_{10}$  reduction over an hour in a 129.7 m<sup>3</sup> chamber

### Unnormalised results

	Q01B	Control §
n=1	2.19	1.06
n=2	2.16	0.93
n=3	2.29	
n=4	2.16	
n=5	2.19	
<b>Mean</b>	<b>2.20</b>	
<b>SD</b>	<b>0.05</b>	<b>0.09</b>
Performance	12.6	27.9

\* Performance measured as duration in seconds to reduce bacterial count in 1m<sup>3</sup> by 1  $\log_{10}$  reduction

§ Expected Control bacterial reduction based on previous results ( $n = 11$ ): 1.07  $\log_{10}$  reductions

### Normalised results

	Q01B	Control ¶
n=1	2.21	1.07
n=2	2.44	1.07
n=3	2.59	
n=4	2.44	
n=5	2.48	
<b>Mean</b>	<b>2.43</b>	
<b>SD</b>	<b>0.14</b>	<b>0.00</b>
Performance	11.4	25.9

\* Performance measured as duration in seconds to reduce bacterial count in 1m<sup>3</sup> by 1  $\log_{10}$  reduction

¶ Q01B results normalised to historical control bacterial reduction values based on previous results ( $n = 11$ ): 1.070  $\log_{10}$  reductions

### Notes

1. The results have been normalised to take into account a lower performance of the standard control for bacterial inactivation for particular measurements. Both unnormalised and normalised results have been included for comparison.
2. Due to methodological reasons, accurate measurement of bacterial numbers at high log reductions was not possible. For this reason, measurements were performed at 5 minute intervals for some measurements to preserve the quality of the data. Calculation of the bacterial CFU reduction curve was conducted on the accurate measurements only.
3. Mean temperature and humidity have been estimated from machine and control values ( $n = 14$ ).
4. A value of 0.264  $\log_{10}$  reductions has been deducted from each result, representing the mean decay in bacterial numbers as measured in the same chamber without any air purification but with air mixing ( $SD = 0.046$ ,  $n = 5$ ).

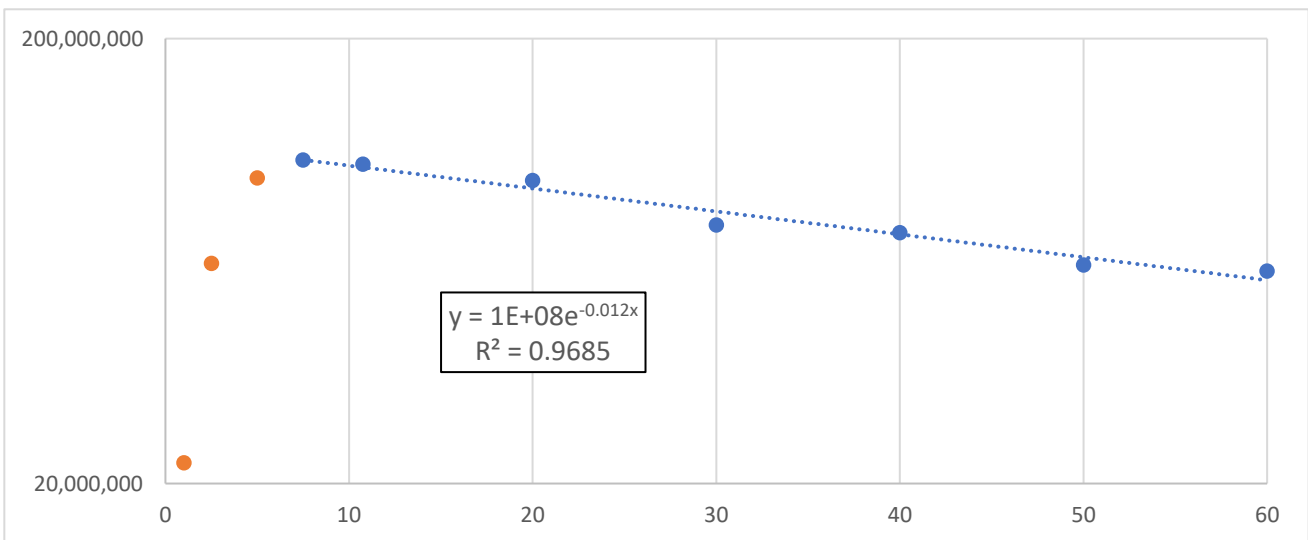
## Room 3 validation: natural decay characteristics

13/04/2022

Validation R3  
n = 1

Plate Count 1	Plate Count 2	Time (mins)	Room Count
3.07E+04	3.80E+04	1	22,270,823
1.00E+05	9.26E+04	2.5	62,436,105
1.56E+05	1.44E+05	5	97,252,500
1.46E+05	1.83E+05	7.5	106,653,575
1.65E+05	1.57E+05	10.75	104,384,350
1.37E+05	1.59E+05	20	95,955,800
1.31E+05	1.04E+05	30	76,181,125
1.04E+05	1.22E+05	40	73,263,550
1.06E+05	8.52E+04	50	61,982,260
9.26E+04	9.26E+04	60	60,037,210

Exponent	-0.012
Intercept	1.00E+08
Calculated 60' count	4.87E+07
Log <sub>10</sub> Reduction	0.31



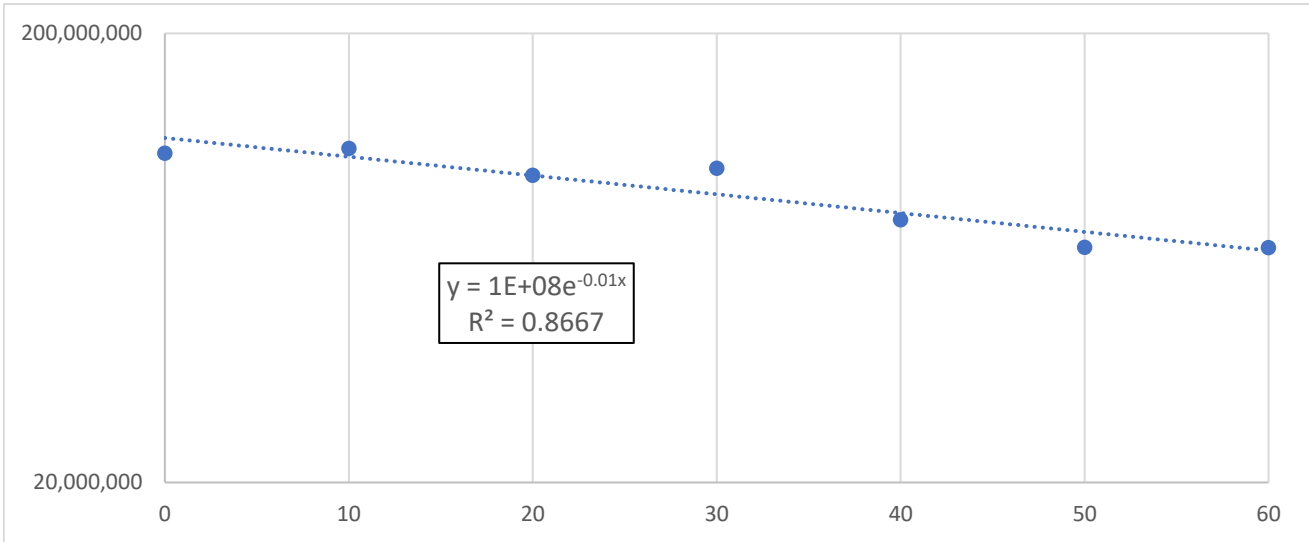
19/04/2022

Validation R3  
n = 2

Plate Count 1	Plate Count 2	Time (mins)	Room Count
1.65E+05	1.69E+05	0	108,274,450
1.59E+05	1.83E+05	10	110,867,850
1.57E+05	1.41E+05	20	96,604,150
1.76E+05	1.33E+05	30	100,170,075
9.81E+04	1.39E+05	40	76,861,893
1.04E+05	1.02E+05	50	66,780,050
9.07E+04	1.15E+05	60	66,682,798

Exponent	-0.010
Intercept	1.00E+08
Calculated 60' count	5.49E+07
Log <sub>10</sub> Reduction	0.26

1 hour trend

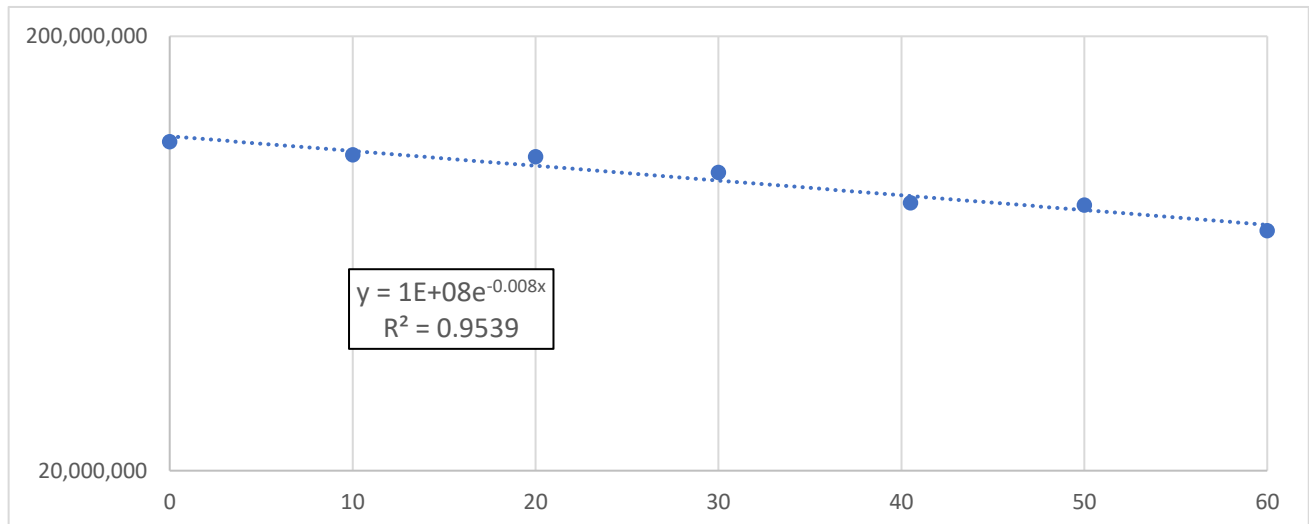


Validation R3  
n = 3

Plate Count 1	Plate Count 2	Time (mins)	Room Count
1.96E+05	1.57E+05	0	114,433,775
1.70E+05	1.59E+05	10	106,653,575
1.52E+05	1.74E+05	20	105,681,050
1.52E+05	1.69E+05	30	97,122,830
1.22E+05	1.33E+05	40.5	82,664,625
1.06E+05	1.46E+05	50	81,692,100
1.24E+05	9.63E+04	60	71,415,753

Exponent	-0.008
Intercept	1.00E+08
Calculated 60' count	6.19E+07
Log <sub>10</sub> Reduction	0.21

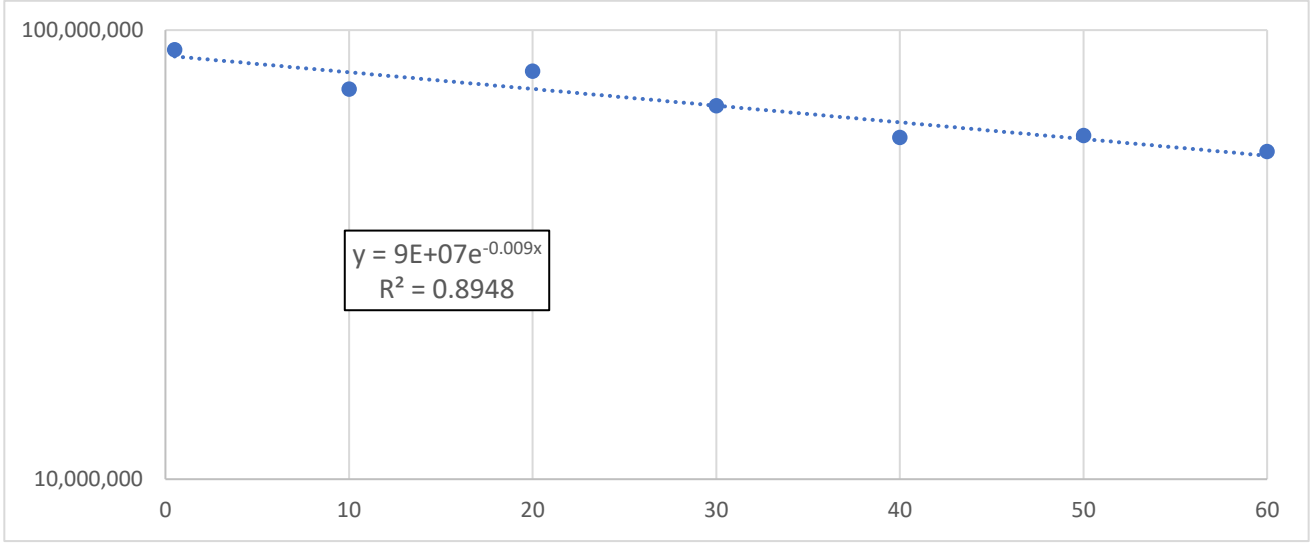
1 hour trend



**Validation R3**  
**n = 4**

Plate Count 1	Plate Count 2	Time (mins)	Room Count
1.33E+05	1.46E+05	0.5	90,444,825
1.11E+05	1.17E+05	10	73,911,900
1.37E+05	1.13E+05	20	81,043,750
8.52E+04	1.24E+05	30	67,817,410
8.89E+04	8.89E+04	40	57,638,315
9.07E+04	8.89E+04	50	58,221,830
7.66E+04	8.89E+04	60	53,650,963

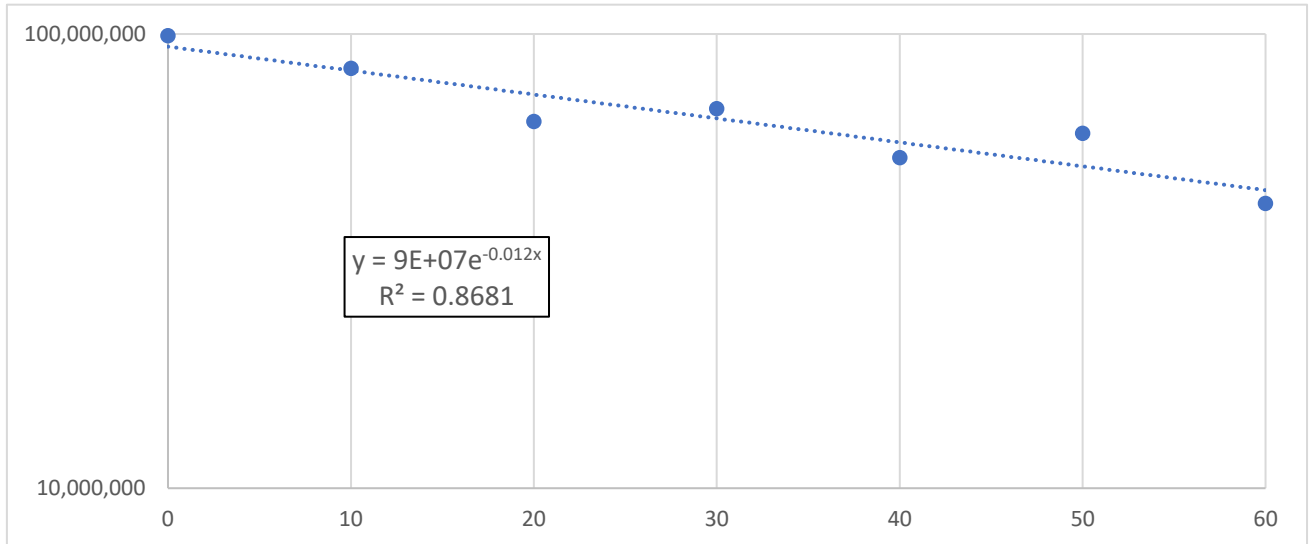
<b>Exponent</b>	-0.009
<b>Intercept</b>	9.00E+07
<b>Calculated 60' count</b>	5.24E+07
<b>Log<sub>10</sub> Reduction</b>	0.23



**Validation R3**  
**n = 5**

Plate Count 1	Plate Count 2	Time (mins)	Room Count
1.65E+05	1.41E+05	0	99,197,550
1.33E+05	1.26E+05	10	83,961,325
1.00E+05	9.81E+04	20	64,219,068
1.13E+05	9.81E+04	30	68,433,343
7.96E+04	8.52E+04	40	53,424,040
1.09E+05	7.74E+04	50	60,426,220
6.86E+04	6.20E+04	60	42,337,255

<b>Exponent</b>	-0.012
<b>Intercept</b>	9.00E+07
<b>Calculated 60' count</b>	4.38E+07
<b>Log<sub>10</sub> Reduction</b>	0.31



## Results summary (bacterial inactivation curve) - natural decay

Log<sub>10</sub> reduction over an hour in a 129.7 m<sup>3</sup> chamber

### *Unnormalised results*

n=1	0.31
n=2	0.26
n=3	0.21
n=4	0.23
n=5	0.31
<b>Mean</b>	<b>0.26</b>
<b>SD</b>	<b>0.05</b>

For and on behalf of the Innovation Agency  
1.11.2022, Dr Nicholas Rhodes PhD & Prof Anthony Fisher PhD MD

Nicholas P. Rhodes



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