Technical Report

# Filtration Efficiency of the Pall BB50T for SARS-CoV-2

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## Introduction

In early December 2019, the first pneumonia cases of unknown origin were identified in Wuhan, the capital city of Hubei province[1]. The pathogen was identified as a novel enveloped RNA beta-coronavirus which currently is named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Patients with the infection were documented both in hospitals and in family settings.

The World Health Organization (WHO) subsequently declared coronavirus disease 2019 (COVID-19) a public health emergency of international concern, i.e. the state of pandemic.
The SARS-CoV-2 pandemic has been and is a big challenge for modern medicine. By April 2021 more than 135 million cases and almost 3 million deaths have been registered by the WHO[2]. About 5 % of patients have been hospitalized with 2.3 % requiring mechanical ventilation[1].

Transmission of the SARS-CoV-2 virus is primarily respiratory in nature. The virion is around 120 nanometers in diameter (60 - 140 nm), and is transmitted in aerosols, which are generated during breathing, coughing, sneezing, speaking and in the medical setting also during aerosol generating procedures associated to mechanical ventilation and respective care of ventilated patients[3]. Virus containing droplets have been shown to be as big as 20 µm in diameter, but the virus may also be transmitted via aerosols, which are less than 5-10 µm size[4].

There is hardly any information about the number of virus particles exhaled by spontaneously breathing or ventilated patients. Numbers can be expected to vary with breathing manoeuvres and ventilation modes and patterns. One study investigated seasonal coronavirus infected patients exhaled and found that up to 200,000 virus particles were coughed-out per hour[5] (approximately 3.3 x$10^3$ per minute).

The Pall BB50T (reorder code BB50T variants) has been tested for filtration efficiency in accordance with ISO 23328-1:2003 Breathing System Filters for anaesthetic and respiratory use Part 1: salt test method to assess filtration performance[6] which is the only international standard for breathing system filter performance testing and uses Sodium Chloride particles of the most penetrating size, 0.1 µm to 0.3 µm as the test agent with an efficiency of approximately 99.98 % when dry and approximately 99.99 % when conditioned in a humidified system in position A as defined in ISO 23328-1 for
24 hours

Additionally, the Pall BB50T has been subjected to testing with a variety of clinically relevant bacteria (including: *Mycobacterium tuberculosis*[7], and *Staphylococcus aureus*[8]) and viruses including, Human Immunodeficiency Virus[9], Hepatitis C Virus[10] and Human Influenza A (H1N1)[11]. Furthermore, the Pall Breathing System Filters have been subjected to testing with bacterial (*Brevundimonas diminuta*) and viral (MS-2 bacteriophage) organisms that represent gold standards for exclusion based on size. These studies have demonstrated the Pall Breathing System Filters offer a 100 % barrier to contaminated liquids and have an airborne bacterial and viral removal efficiency of at least 99.999 %.

Coronavirus species have a single stranded RNA and their size ranges from 120 nm to 160 nm which is considerably larger than the 27 nm MS-2 bacteriophage. Based on the size of the SARS-CoV-2 there would be no reason to expect that Pall Breathing System Filters would not be effective with regards to prevention of the passage of SARS-CoV-2.
This study was conducted to test the filtration efficiency of Pall BB50T using Sars-CoV-2 Heat inactivated 2019 Novel Coronavirus in droplets of approximately 3 µm using the principles of ASTM F2101-19[12] and EN 14683:2019[13].

## Materials and Methods

Pall BB50T were analyzed for their ability to retain aerosolized heat inactivated 2019 Novel Coronavirus (SARS-CoV-2) Isolate USA-WA1/2020.

The test apparatus (Figure 1) consisted of an aerosol nebulizer which produced 3 µm aerosol droplets, as required by EN 14683:2019 (Medical Face Masks) connected to the patient side of the Pall BB50T and an Andersen cascade impactor downstream of the Pall BB50T. A vacuum pump was used to pull the viral aerosol through the Andersen Cascade Impactor at 28 L/min.

The presence of the viral challenge on the Andersen impactor (with or without the Pall BB50T between the nebulizer and the Andersen impactor) was determined by swabbing the Andersen cascade impactor, followed by extraction using a CommaXP virus DNA/RNA extraction kit (Generon, EXD199) and detection by RT-PCR using an ETfinder RT-PCR kit: COVID 19 (Gene RdRp) on an AriaMx Real-Time PCR System (Agilent CA).

Efficiency of the test apparatus and loss of the viral challenge to the system was evaluated by running the apparatus without the Pall BB50T between the nebulizer and the Andersen impactor.

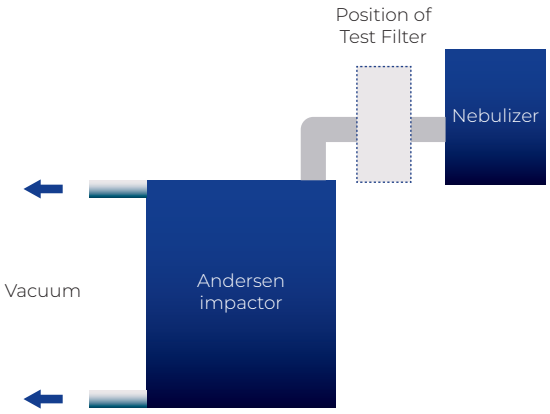


Figure 1: Diagrammatic representation of the test apparatus

## Results

### SARS-CoV-2 test apparatus detection efficiency

Table 1 shows the total viral challenge nebulized through the test apparatus without a filter in place and the viral load detectable on the downstream Andersen impactor and $log_{10}$ loss to the apparatus. This data shows that without a Pall BB50T in place the viral challenge is detectable on the Andersen impactor with a loss to the apparatus of approximately 1.11 $Log_{10}$.

**Table 1. Total SARS-CoV-2 challenge from the nebulizer and viral load detected on the Andersen Impactor**

| Challenge viral load Genomic copies ($Log_{10}$ genomic copies) | Impactor recovery Genomic copies ($Log_{10}$ genomic copies) | $Log_{10}$ loss to rig |
|---|---|---|
| $1.15 \times 10^{10}$ (10.06) | $1.02 \times 10^{9}$ (9.01) | 1.05 |
| $3.82 \times 10^{10}$ (10.58) | $4.80 \times 10^{9}$ (9.68) | 0.9 |
| $5.16 \times 10^{10}$ (10.71) | $4.00 \times 10^{9}$ (9.60) | 1.11 |

## SARS-CoV-2 nebulization challenge of the Pall BB50T

Table 2 shows the actual viral challenge (nebulized viral challenge - 1.11 $Log_{10}$ loss to the apparatus) and the SARS-CoV-2 viral load detected on the Andersen impactor downstream of the Pall BB50T. The Pall BB50T filter efficiency for removal of the SARS-CoV-2 aerosol challenge is shown as percentage reduction and $Log_{10}$ reduction.

**Table 2. Pall BB50T SARS-CoV-2 Challenge results**

| Filter | Corrected Viral challenge ($Log_{10}$ genomic copies) | Viral recovery downstream of BB50TE ($Log_{10}$ genomic copies) | Virus Filtration Efficiency % | $Log_{10}$ reduction |
|---|---|---|---|---|
| 1 | $9.55 \times 10^8$ (9.52) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.68 |
| 2 | $6.31 \times 10^8$ (8.80) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.50 |
| 3 | $5.13 \times 10^8$ (8.71) | 2108 (3.32) | > 99.999 | 5.39 |
| 4 | $6.03 \times 10^8$ (8.78) | $2 \times 10^3$ (<3.30) | > 99.999 | 5.48 |
| 5 | $3.16 \times 10^9$ (8.48) | $2 \times 10^3$ (<3.30) | > 99.999 | 5.18 |
| 6 | $4.90 \times 10^8$ (8.69) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.39 |
| 7 | $5.75 \times 10^8$ (8.76) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.46 |
| 8 | $4.47 \times 10^8$ (8.65) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.35 |
| 9 | $4.68 \times 10^8$ (8.67) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.37 |
| 10 | $6.61 \times 10^8$ (8.82) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.52 |
| 11 | $5.75 \times 10^8$ (8.76) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.46 |
| 12 | $3.02 \times 10^9$ (9.48) | 4370 (3.64) | > 99.999 | 5.84 |
| 13 | $1.86 \times 10^9$ (9.27) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.97 |
| 14 | $2.45 \times 10^9$ (9.39) | 2680 (3.43) | > 99.999 | 5.96 |
| 15 | $1.48 \times 10^9$ (9.43) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 6.13 |
| 16 | $2.75 \times 10^9$ (9.44) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 6.14 |
| 17 | $1.10 \times 10^9$ (9.04) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.76 |
| 18 | $1.38 \times 10^9$ (9.14) | 8330 (3.92) | > 99.999 | 5.22 |
| 19 | $1.00 \times 10^9$ (9.00) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.70 |
| 20 | $2.00 \times 10^9$ (9.30) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 6.00 |
| 21 | $2.24 \times 10^9$ (9.35) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 6.05 |
| 22 | $1.02 \times 10^9$ (9.01) | $< 2 \times 10^3$ (<3.30) | > 99.999 | > 5.71 |

If no RT-PCR signal was detected, $< 2 \times 10^3$ (<3.3 $Log_{10}$) was reported

## Conclusions

Pall BB50T were tested for their ability to retain a challenge of aerosolized heat inactivated SARS-CoV-2. The data presented here showed that the Pall BB50T are able to retain > 99.999 % of SARS-CoV-2 when challenged with > $10^8$ genomic copies, equivalent to a reduction of more than Log 5.

## References


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