REPORT

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Bacterial filtration efficiency of medical face mask

(1 appendix)

Assignment

Evaluate bacterial filtration efficiency (BFE) of a medical face mask following the guideline of SS-EN 14683:2019 section 5.2.2.

Test item

Test item delivered to RISE:

1. Medical Mask SAFE® Type IIR / ES

Figure 1. Package of the test item

Methods

While wearing gloves, the test item was placed in a humid chamber and conditioned overnight at 85% ± 5 relative humidity, for minimum four hours.

Bacterial suspension of *Staphylococcus aureus* (ATCC 6538) with a concentration of 1 x 10^4 colony forming units (CFU) per mL was prepared in peptone water. The inoculum was serially diluted and plated on tryptic soy agar (TSA) for CFU count.

A 10 ml syringe was filled with the bacterial suspension and mounted to a nebulizer, adjusted to deliver one mL suspension in one minute. Aerosols were formed by applying air pressure of 35 kPa to the specified volume of bacterial suspension delivered into the aerosol chamber by the nebulizer at a controlled speed. The aerosols were drawn through a six stage impactor by the means of a vacuum pump. At each of the six stages in the impactor a TSA agar plate was mounted, collecting the aerosols of defined size at each stage, according to table 1. Aerosols were produced for one minute, followed by one minute air, for each sample except the negative control were two minutes air was applied, without bacterial aerosols. A minimum of

two positive controls (without face mask) were sampled, one prior to the tested face masks and one after. The negative control, without bacterial suspension or face mask, was sampled last. The face masks, one at a time, was mounted as shown in figure 1, with the inside facing the aerosol challenge. For each of the five tested face masks, as well as controls, aerosols were collected on six agar plates.

The ends of the face masks were cut off in order to mount them flat in the impactor. A circular area with a diameter of 8 cm was tested for each face mask, resulting in an area of ~50 cm^2.

The agar plates were incubated at 37°C and CFU counted the next day, see pictures in appendix 1. Following SS-EN 14683, actual number of CFUs on agar plates from stage one and two are used in the analysis while the number of CFUs on agar plates from stage three to six are converted according to the positive hole conversion table, described by Andersen (1958).

The percent bacterial filtration efficiency of the five test samples were calculated as a reduction in number of CFU compared to the mean of the positive controls.

Table 1. The six stages of the impactor

Stage	Size of aerosols (µm)
1	7 and larger
2	4,7 -7
3	3,3 – 4,7
4	2,1 – 3,3
5	1,1 – 2,1
6	0,65 – 1,1

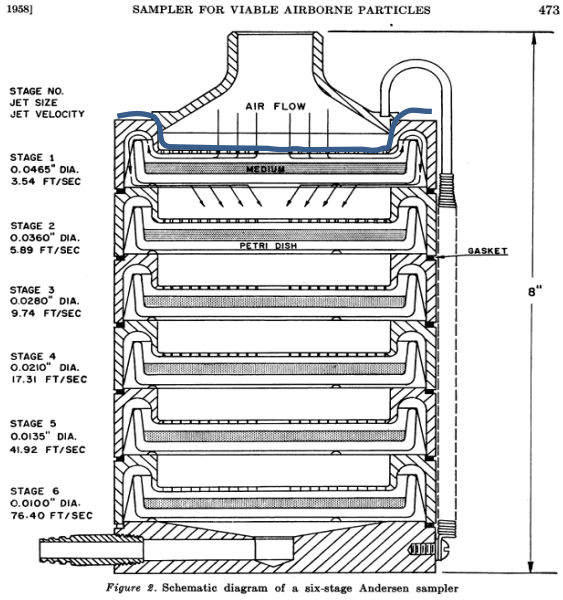

Figure 2. Schematic diagram of a six-stage Andersen sampler

Figure 2. Schematic figure of the impactor, were the face mask is placed as shown by the blue line.

Results

Test parameters:

- The mean particle size (MPS): 2,3 µm
- Challenge per sample: 1,4 x 10^3 CFU
- Area of face mask tested: ~50 cm^2
- Mean number CFU per negative control: 0

The test parameters deviates from the standard in that the MPS is slightly smaller, i.e. 2,3 µm instead of 2,7-3,3 µm and the aerosol challenge is slightly lower, i.e. 2,3 x 10^3 CFU instead of 2,7 - 3,0 x 10^3 CFU/sample as recommended in the standard.

Mean bacterial filtration efficiency (BFE) of the test item, “Medical Mask SAFE® Type IIR / ES“ (n=5), was 99,9 % ± 0,12.

Table 2. BFE for each test specimen

Medical Mask SAFE® Type IIR / ES	**BFE (%)**
1	100,0
2	100,0
3	99,9
4	99,7
5	100,0

Conclusion

The test item, “Medical Mask SAFE® Type IIR / ES” fulfilled the requirement of Type II masks, with a filtration efficiency above 98% for all five samples.

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References

1. SS-EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods
2. Andersen, Ariel A. "NEW SAMPLER FOR THE COLLECTION, SIZING, AND ENUMERATION OF VIABLE AIRBORNE PARTICLES." The Journal of Bacteriology 76.5 (1958): 471-484.

Appendices

1. Photos

Photos

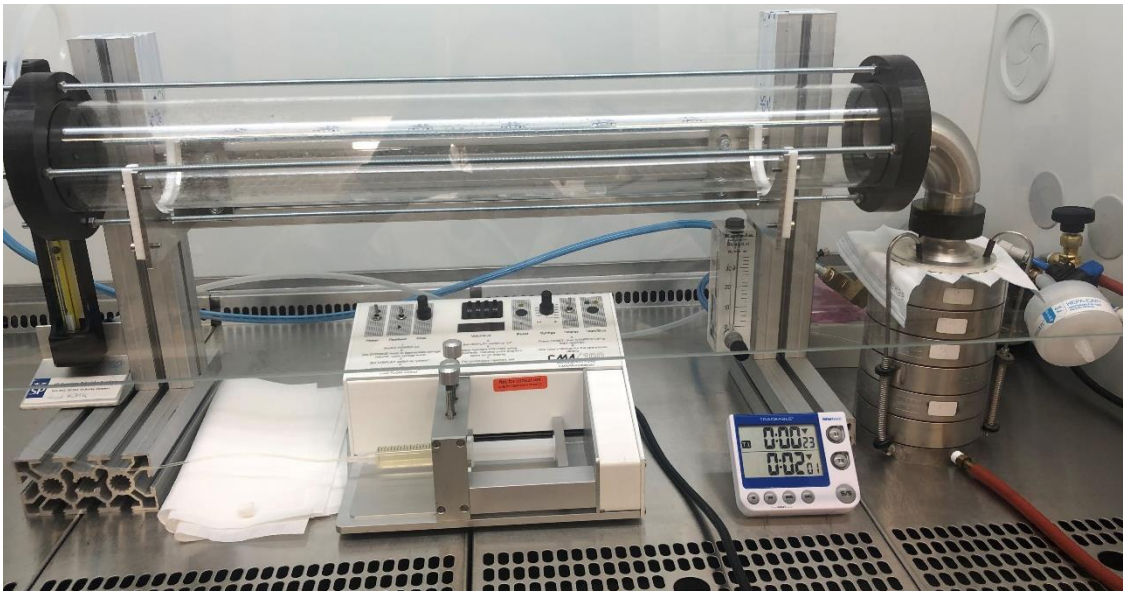

Figure A1: Set-up with a test item mounted in the impactor.

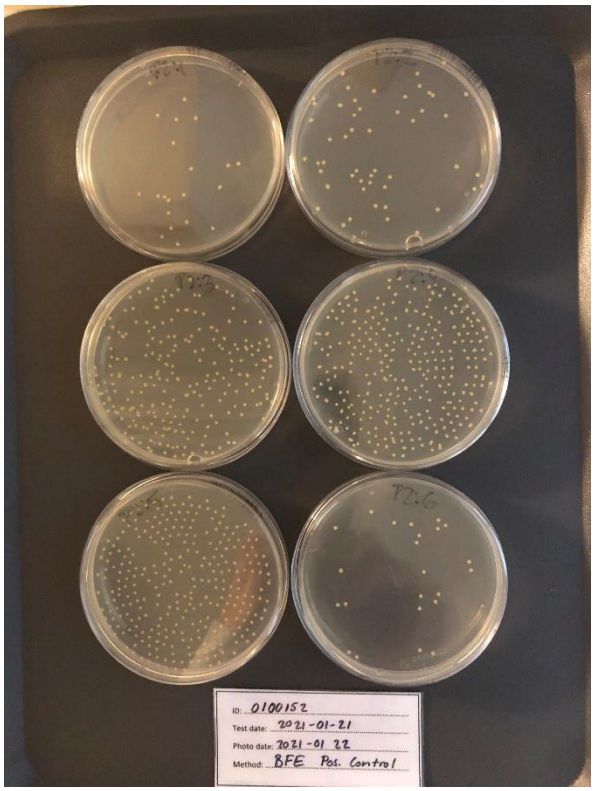

Figure A2: Typical CFU distribution on agar plates from positive controls

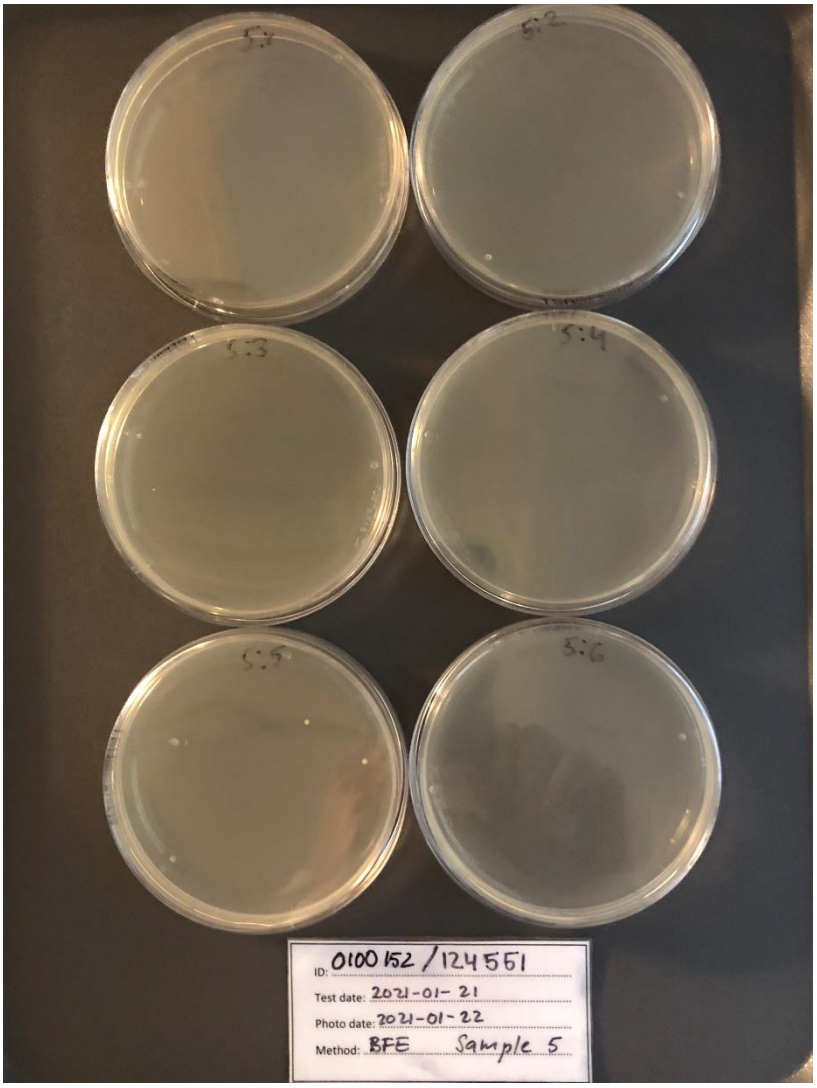

Figure A3: Typical CFU distribution on agar plates were the aerosols have been filtered through face mask 5 of 5 from product “Medical Mask SAFE® Type IIR / ES”.