

EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.

AB-0583-T

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10-20

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: EN 14683:2019+AC:2019 Medical Face Masks, Requirements and Test Methods
A specimen of the mask material is clamped between an impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

ORIGINAL

Test Flow Rate	28,3 L/min
Test Flow Time	2 minute
Sample Sizes	5 pieces
Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Bacterial concentration (cfu/ ml)	5x10 ⁵ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	2,74x10 ³ cfu/ ml

RESULTS

Number of Test Sample	Test Sample (T) Number of Bacteria (cfu/ml)	Bacterial Filtration Efficiency (% B)	Requirement BFE (%)
1	241	%91.2	≥90
2	236	%91.4	
3	230	%91.6	
4	224	%91.8	
5	254	%90.7	

cfu: Colony-forming unit

$$B = (C - T) / C \times 100$$

%B: Bacterial Filtration Efficiency

C: is the mean of the total plate counts for the two positive control runs

T: is the total plate count for the test specimen

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A specimen of the mask material is clamped between an impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

AFTER WASH

Test Flow Rate	28,3 L/min
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Microorganism	<i>Staphylococcus aureus</i> ATCC 6538
Washing Cycle	5
Washing Method	6N@60°C Line Dry/ (TS EN ISO 6330). 2012
Bacterial concentration (cfu/ ml)	5x10 ⁵ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	2,74x10 ³ cfu/ ml

RESULTS

Number of Test Sample	Test Sample (T) Number of Bacteria (cfu/ml)	Bacterial Filtration Efficiency (% B)	Requirement BFE (%)
1	265	%90.3	≥90
2	271	%90.1	
3	251	%90.8	
4	258	%90.6	
5	2268	%90.2	

cfu: Colony-forming unit

$$B = (C - T) / C \times 100$$

%B: Bacterial Filtration Efficiency

C: is the mean of the total plate counts for the two positive control runs

T: is the total plate count for the test specimen

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TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

ORIGINAL

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/g)	17 cfu/g	≤ 30 cfu/g

*cfu= Colony forming unit.

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

(After 5 washes, 6N@60°C Line Dry) / TS EN ISO 6330:2012

AFTER WASH

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/g)	8 cfu/g	≤ 30 cfu/g

*cfu= Colony forming unit.