

Microbiological examination on GenSwabs & GenSwabs EtO according to ISO 8784-1:2015 and ISO8784-3:2019

The goal of this evaluation is to determine microbiological charge of GenSwab and GenSwabs EtO based on disintegration according to NF ISO 8784-1:2015 for bacteria and bacteria spores and according to PR NF ISO 8784-3:2019 for yeast and mould.

Samples:

- GenSwab card CAT.73000-000 LOT 1005 named GenSwab
- GenSwab card CAT.73000-000 LOT 1005 treated with ethylene oxide named GenSwab EtO

Methods:

- **ISO 8784-1:2014 - Microbiological examination - Enumeration of bacteria and bacterial spores based on disintegration.**

- **Reagents:**

Diluant: Ringer + Tween 80 solution

Culture media: tryptone glucose extract agar

- **Apparatus and materials:**

Disintegrator electrical blender: 1min - low level

Incubator: 32°C- 48H

Petri dishes 90mm diameter

- **Sampling:**

- GenSwab: 1.43g diluted on 143mL of Ringer+Tween 80 solution.
- GenSwab EtO: 1.41g diluted on 141mL of Ringer+Tween 80 solution.

- **Calculation:**

Total number of bacteria and bacteria spores is calculated according to formula:

$$N_{rec} = n \cdot V \cdot F / (v \cdot m)$$

Nrec: Total number of bacteria or bacterial spore is calculated in CFU per gram of sample

N: Total number of colonies from 5 Petri dished expressed in UFC

F: Dilution factor

V: volume of tested sample

V: Volume of seeded fibrous suspension

M: mass of sample for the test

- **ISO8784-3:2019 - Microbiological examination - Enumeration of yeast and mold based on disintegration.**

- **Reagents:**

Diluant: Ringer + Tween 80 solution

Culture media: Potato dextrose agar

- **Apparatus and materials:**

Disintegrator electrical blender: 1 min - low level

Incubator: 25°C- 5 days

Petri dishes 90mm diameter

- **Sampling:**

- GenSwab: 1.43g diluted on 143mL of Ringer+Tween 80 solution.
- GenSwab EtO: 1.41g diluted on 141mL of Ringer+Tween 80 solution.

- **Calculation:**

Total number of yeast and mold is calculated according to following formula:

$$N_{rec} = n \cdot V \cdot F / (v \cdot m)$$

Nrec: Total number of yeast and mold is calculated in CFU per gram of sample

N: Total number of colonies from 5 Petri dished expressed in UFC

F: Dilution factor

V: volume of tested sample

V: Volume of seeded fibrous suspension

M: mass of sample for the test

Results:

For each sample and each micro-organism, total number of colony-forming units (Nrec) obtained after incubation are summarized in the table below for 90mm Petri Dishes and 10ml of suspension:

Sample	Bacteria	Bacterial spores	Yeast and mold
GenSwab	≤10 UFC/g	≤10 UFC/g	≤10 UFC/g
GenSwab EtO	≤10 UFC/g	≤10 UFC/g	≤10 UFC/g

Conclusions:

Tested samples of GenSwab and EtO GenSwab are free of microbial contamination.

Ethylene oxide treatment does not affect antimicrobial properties of GenSwabs.

Operator: Aurore Legast

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