



ViriMASK, Ltd. Document Control

01 May 2020

**Document:**

Release of Aminolab Laboratories Final Report for Microbial Cleanliness for Face Masks.

**Terms:**

- The Microbial Cleanliness test (Bioburden) is performed on finished product. This testing is performed to demonstrate that the manufacturing process is in control and is required by EN 14683:2019.
- CFU/gram, the number of colony-forming units in each a gram of the sample.

**Summary:**

The Microbial Cleanliness test determines the total number of viable microorganisms on the product using an extraction method. The total viable aerobic microbial count and fungal enumeration is determined. Based on the weight of the product, the results are reported as the total bioburden per gram tested for each sample.

According to EN 14683, in order to meet the performance requirements of Type IIR, the bioburden of the face mask shall be  $\leq 30$  cfu/g.

**Results:**

The bioburden of the ViriMASK samples met the acceptance criteria.

For more information, contact [info@virimask.com](mailto:info@virimask.com)

ViriMASK Ltd. & OHK Medical Devices, Inc are subsidiaries of Oneg HaKarmel Ltd., Tirat Carmel,  
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01.05.2020  
 Report No: 12990.20  
 Page 1 of 1

## Bioburden Estimation

Producer:	Onco Ha Karmel Ltd
Tel:	+972-4-8242369
Email:	
Test Date:	26.04.2020
Sampled by:	Customer
Sample description:	VM-RM-201
Order No.:	P020000024
Aminolab No:	031331.20-M-031333.20-M

### References:

1. ANSI/AAMI/ISO 11737-1:2018, Sterilization of health care products- Microbiological methods- Part 1; Determination of a population of microorganisms on products
2. Aminolab SOP No. 50.WL106/ Version 6: Bioburden test- Pre Sterilization Estimation of population of Microorganisms on/in Medical Devices.

### Method:

Each sample was aseptically weighed, transferred from the packaging into a sterile container with 500ml of sterile 0.9% saline with 0.1% tween 80, mechanically shaken for 20 minutes at 300RPM and the extract was filtered through 0.45µm membrane filter. Each filter was placed onto TSA plate and incubated for 2 days at 30-35°C and then for additional 3 days at 20-25°C.

### Test Results:

Aminolab No.	Bacterial colony count (CFU/sample)	Fungal colony count (CFU/sample)	TAMC (CFU/sample)	Weight (gram)	Bioburden CFU/gram
031331.20-M	127	0	127	57	3
031332.20-M	111	6	117	54	3
031333.20-M	133	4	137	57	3

**Acceptance Criteria:** ≤30 CFU/gram

**Conclusion:** The samples met the acceptance criteria.

Examined by Mila Pechersky M.Sc: Deputy Head of Microbiology Division

Confirmed by Helena Ashkenazi, Ph.D, Head of Microbiology Division:



This certificate is valid only when it is presented in its complete format, and it is not permitted to extract part for inclusion in any other document. The data presented, accurately expresses the results for the sample received only. It is not permitted to use Aminolab LTD's name or its reputation in respect to the above - specified results without Aminolab written consent.

\* End of certificate of analysis \*

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