Nelson Labs
A Sotera Health company

Sponsor:
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UNITED KINGDOM

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Cambridge Mask Pro Admiral Size Large 5060437942118
Study Number:	1313387-S01
Study Received Date:	25 Jun 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202003597 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	23.6	29	13	41.6	1.8
2	25.5	22	6[a]	27.8	1.1
3	25.6	33	9[a]	42.3	1.7
4	23.9	70	13[a]	82.4	3.4
5	23.7	15	40	55.0	2.3
Recovery Efficiency	18.0%				

Note: The results are reported as colony forming units (CFU) per mask.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

Robert Putnam electronically approved — 14 Jul 2020 15:10 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time