

Work Order	3212.2
Setup-Code	181029-10290-2801-02



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

*Coated Leneta-Foil vs. Enterococcus hirae DSM3320
ATCC10541*

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Report on Findings

Client: NANO4LIFE EUROPE L.P.
Address: Vouliagmenis Ave. 318
 Ag. Dimitrios – 173 43
 Athens/Greece

Work order no.: 3212.2

Test object: Coated Leneta-Foil vs. *Enterococcus hirae* DSM3320 ATCC10541

Sample description: Coated Leneta-Foil

Date of receipt of sample: 2018-Oct-22

Type of test: JIS Z 2801:2012 Antimicrobial products – Test for antimicrobial activity and efficacy

Test Germ: *Enterococcus hirae* DSM3320 ATCC10541

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
 90411 Nuremberg, Germany

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Sample material: n.b.

No. of pages in report: 7

Report on findings to the client: **Place and date of preparation:** Nuremberg, 2018-Nov-07
Recipient: NANO4LIFE EUROPE L.P.

Laboratory Director: _____
 Harald Gerauer, Laboratory Director
 QualityLabs BT GmbH

Released: _____
 Markus Zehe, Managing Director
 QualityLabs BT GmbH

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Declaration on Quality Assurance

This investigation was performed and supervised according to the standard operating procedure "SOP zu JIS Z 2801:2012 (Mod)" by QualityLabs BT GmbH. The laboratory and process are continually monitored by independent, external authorities, as well as by internal audits.

Archiving

A copy of the test report, a protocol of the measurement as well as the accompanying correspondence and business records are archived by QualityLabs BT GmbH. The retention period is at least 10 years.

Test description

Anti-bacterial activity is determined in accordance with a modified version of JIS Z 2801:2012.

During the test, a thin liquid-film containing the bacteria (1.25×10^4 CFU / cm²) is applied directly to the test sample (Standard: 5 cm x 5 cm). To avoid desiccation a foil (Standard: 4cm x 4cm, Stomacher Bags) is applied. Immediately after inoculation, the bacteria from the reference sample are separated from the sample and the enveloping foil surfaces using ultrasound and vortex devices and the number of viable germs (CFU – colony-forming units) is determined (t_0 value). A further set of reference samples and samples given anti-microbial treatment is incubated with bacteria in a liquid-film and the enveloping foil in a damp environment at 37°C. After 24 hours, the bacteria are separated from the sample surfaces using ultrasound and vortex devices and the number of viable germs is determined (t_{24} value).

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Assessment of antimicrobial activity

A logarithmic germ reduction of ≥ 3 log scales of the antimicrobial sample in comparison to the respective reference is used as assessment criterion to pass the antimicrobial test.

Germ reduktion [log scales]	Antibacterial activity
< 3	Not sufficient antimicrobial activity
≥ 3	Sufficient antimicrobial activity

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References to Testconditions

Testconditions		
Sample size	25	cm ²
Foil size	16	cm ²
Volume Inoculum	300	μl
Sample cleaning		-

References to deviations, preincubations, special test conditions

NONE

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Test Results

Sample Name		Sample Code	t ₀ (cells/cm ²)			t ₂₄ (cells/cm ²)			Reduction [%]	Log Reduction
1	Reference	102902310180011	7.3 x 10 ⁴	9.7 x 10 ⁴	7.3 x 10 ⁴	8.3 x 10 ⁴	1.0 x 10 ⁵	8.0 x 10 ⁴		Reference
2	NANO4-CLEAN/PRIME + NANO4-HYGIENE LIFE	102902310180012				< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	> 99.99	> 4

*see "Interpretation of Results", page 6

Test strain	<i>Enterococcus hirae</i> DSM3320 ATCC10541
Initial cell count inoculum / cm ²	1.25 x 10 ⁴
Initials of the editor	MZ
Measurement ended on	Nov-05-2018

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Comments on test objects

NONE

Interpretation of the results based on the measurements

NONE

Editor: Mr. Zehe _____

Crosschecked: Mr. Mannala _____

References

JIS Z 2801:2012 Antimicrobial products – Test for antimicrobial activity and efficacy