

Work Order	3109.2
Setup-Code	180611-10290-2801-02



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

Coated Leneta-Foil vs. Staph. aureus DSM 21979

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Report on Findings

Client: Nano-Care UK (Signo-Nanocare UK Ltd)
Address: PO Box 225, Oswestry, Shropshire, SY10 1DL, UK +44 1691 654 282

Work order no.: 3109.2

Test object: Coated Leneta-Foil vs. Staph. aureus DSM 21979

Sample description: Coated Foil

Date of receipt of sample: 08.06.2018

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

Test Germ: Staphylococcus aureus DSM21979 EDCC 5247

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
90411 Nuremberg, Germany

Setup-Code: 180611-10290-2801-02

Sample material: Leneta Foil

No. of pages in report: 7

Report on findings to the client: **Place and date of preparation:** Nuremberg, 13.9.2018
Recipient: Nano-Care Deutschland AG

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	400	µl
Sample cleaning	Isopropanol	-

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 Leneta-Folie P121-10 (Reference)	102900806180001	9.0 x 10 ⁴	1.1 x 10 ⁵	1.1 x 10 ⁵	5.1 x 10 ⁵	4.1 x 10 ⁵	5.3 x 10 ⁵	-	-
2 Liquid Guard clean + primer + wipe	102900806180002				< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	> 99.99	> 4
3 Liquid Guard pro + wipe	102900806180003				< 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>Staphylococcus aureus DSM21979 EDCC 5247</i>
Initial cell count inoculum / cm ²	1.25 x 10 ⁴
Initials of the editor	MZ
Measurement ended on	Mar-12-20xx

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Comments on test objects

NONE

Interpretation of the results based on the measurements

NONE

Editor: Mr. Zehe _____

Crosschecked: Mr. Shendi _____

References

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