

Work Order	3353.2_Rev4
Setup-Code	200115-10290-2801-01



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

*Coated Leneta-Foil versus Staphylococcus aureus
DSM21979 EDCC 5247 after 225 days of artificial aging*

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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.: 3353.2_Rev4

Test object: Coated Leneta-Foil versus *Staphylococcus aureus* DSM21979 EDCC 5247 after 225 days of artificial aging

Sample description: Coated foil

Date of receipt of sample: 23.05.2019

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: 200115-10290-2801-01

Sample material: Test plates

No. of pages in report: 7

Report on findings to the client: **Place and date of preparation:** Nuremberg, 24th of April 2020
Recipient: Nano-Care Deutschland GmbH
This revision replaces the test report from the 27th of January 2020

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	-	-

References to deviations, preincubations, special test conditions

The samples were stored for 225 days at 50 °C, which corresponds to an artificial aging of 4 years according to ASTM F 1980.

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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 sample	102902805190017	4.7 x 10 ⁴	5.8 x 10 ⁴	5.8 x 10 ⁴	1.5 x 10 ⁵	1.5 x 10 ⁵	1.7 x 10 ⁵	-	Reference
2 Liquid Guard 2,9%	102902805190018				< 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</i> DSM21979 EDCC 5247
Initial cell count inoculum / cm ²	1.25 x 10 ⁴
Initials of the editor	MZ
Measurement ended on	Jan-27-2020

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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