

Work Order	3250
Setup-Code	181218-10290-2801-01



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

Coated Leneta-Foil versus Clostridioides difficile DSM 27543

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Report on Findings

Client: Nano-Care Deutschland GmbH
Address: Alfred-Nobel-Straße 10
66793 Saarwellingen

Work order no.: 3250

Test object: Coated Leneta-Fiol versus *Clostridioides difficile* DSM 27543

Sample description: coated 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: *Clostridioides difficile* DSM 27543

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
90411 Nuremberg, Germany

Setup-Code: 181218-10290-2801-01

Sample material: n.b.

No. of pages in report: 7

Report on findings to the client: Place and date of preparation: Nuremberg, 2018-Dez-18
Recipient: Nano-Care Deutschland GmbH

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 reduction [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

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 sample	102902310180011	1.1 x 10 ³	8.3 x 10 ²	6.0 x 10 ²	2.3 x 10 ²	1.5 x 10 ²	1.5 x 10 ²		Reference
2	Liquid Guard 2,9%	102902310180012				< 1.0 x 10 ¹	< 1.0 x 10 ¹	< 1.0 x 10 ¹	> 99.99	3.45

*see "Interpretation of Results", page 6

Test strain	<i>Clostridioides difficile</i> DSM 27543
Initial cell count inoculum / cm²	1.25 x 10 ⁴
Initials of the editor	MZ
Measurement ended on	Dec-12-2018

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Comments on test objects

NONE

Interpretation of the results based on the measurements

Due to the test germ used *Clostridioides difficile* DSM 27543 exclusively grows anaerobic, under exclusion of air, the test specimens, and the agar plates were incubated after inoculation and incubation at 37 ° C in anaerobic pots. However, relatively low growth was seen on the blank immediately after inoculation (t0) and after incubation (t24). But there was a significant reduction in germs due to the Liquid Guard 2.9% coated Leneta film (102902310180012) compared to the blank sample (102902310180011).

Editor: Mr. Zehe _____

Crosschecked: Mr. Shendi _____

References

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