

Work Order	3109.3
Setup-Code	180611-10290-2801-03



Test Report

JIS Z 2801:2012 (Mod)

Antimicrobial products – Test for antimicrobial activity and efficacy

Test Object:

Coated Leneta Foil vs. Klebsiella pneumoniae DSM 6135

Work Order	3109.3
Setup-Code	180611-10290-2801-03

Report on Findings

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

Work order no.: 3109.3

Test object: Coated Leneta Foil vs. Klebsiella pneumoniae DSM 6135

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: Klebsiella pneumoniae DSM6135

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
 90411 Nuremberg, Germany

Setup-Code: 180611-10290-2801-03

Sample material: Leneta Foil

No. of pages in report: 7

Report on findings to the client: **Place and date of preparation:** Nuremberg, 14.9.2018
Recipient: Nano-Care Deutschland AG

Laboratory Director:

 Harald Gerauer, Laboratory Director
 QualityLabs BT GmbH

Released:

 Markus Zehe, Managing Director
 QualityLabs BT GmbH

Work Order	3109.3
Setup-Code	180611-10290-2801-03

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).

Work Order	3109.3
Setup-Code	180611-10290-2801-03

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

Work Order	3109.3
Setup-Code	180611-10290-2801-03

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

Work Order	3109.3
Setup-Code	180611-10290-2801-03

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	2.1 x 10 ⁴	3.6 x 10 ⁴	8.0 x 10 ⁴	2.7 x 10 ⁵	3.8 x 10 ⁵	2.7 x 10 ⁵	-	-
2	Liquid Guard clean + primer + wipe	102900806180002				6.4 x 10 ²	7.5 x 10 ¹	< 1.0 x 10 ¹	99.92	3.11
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>Klebsiella pneumoniae DSM6135</i>
Initial cell count inoculum / cm ²	1.25 x 10 ⁴
Initials of the editor	MZ
Measurement ended on	Mar-12-20xx

Work Order	3109.3
Setup-Code	180611-10290-2801-03

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