

Work Order	3332
Setup-Code	190508-10290-2801-01



## Test Report

### JIS Z 2801:2012 (Mod)

**Antimicrobial products – Test for antimicrobial activity and efficacy**

#### **Test Object:**

*Coated Leneta-Foils against Enterococcus hirae DSM3320  
ATCC10541 after 3 years of artificial aging*

Work Order	3332
Setup-Code	190508-10290-2801-01

## Report on Findings

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

**Work order no.:** 3332

**Test object:** Coated Leneta-Foils against Enterococcus hirae DSM3320 ATCC10541 after 3 years of artificial aging

**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

**Setup-Code:** 190508-10290-2801-01

**Sample material:** n.b.

**No. of pages in report:** 7

**Report on findings to the client:** **Place and date of preparation:** Nuremberg, 2019-May-14  
**Recipient:** Nano-Care Deutschland GmbH

**Laboratory Director:** \_\_\_\_\_  
Harald Gerauer, Laboratory Director  
QualityLabs BT GmbH

**Released:** \_\_\_\_\_  
Markus Zehe, Managing Director  
QualityLabs BT GmbH

Work Order	3332
Setup-Code	190508-10290-2801-01

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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 ( $1.25 \times 10^4$  CFU / cm<sup>2</sup>) 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	3332
Setup-Code	190508-10290-2801-01

### Assessment of antimicrobial activity

A logarithmic germ reduction of  **$\geq 3$  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
$\geq 3$	Sufficient antimicrobial activity

Work Order	3332
Setup-Code	190508-10290-2801-01

**References to Testconditions**

Testconditions		
Sample size	25	cm <sup>2</sup>
Foil size	16	cm <sup>2</sup>
Volume Inoculum	400	µl
Sample cleaning	-	-

**References to deviations, preincubations, special test conditions**

The samples were stored for 169 days at 50° C, which corresponds to an artificial aging of 3 years according to ASTM F 1980.

Work Order	3332
Setup-Code	190508-10290-2801-01

### Test Results

Sample Name	Sample Code	t <sub>0</sub> (cells/cm <sup>2</sup> )			t <sub>24</sub> (cells/cm <sup>2</sup> )			Reduction [%]	Log Reduction
1 Nullprobe	102902310180011	1.0 x 10 <sup>5</sup>	1.0 x 10 <sup>5</sup>	7.3 x 10 <sup>4</sup>	1.4 x 10 <sup>5</sup>	1.5 x 10 <sup>5</sup>	1.3 x 10 <sup>5</sup>	-	Reference
2 Liquid Guard 2,9%	102902310180012				< 1.0 x 10 <sup>1</sup>	< 1.0 x 10 <sup>1</sup>	< 1.0 x 10 <sup>1</sup>	> 99.99	> 4

\*see "Interpretation of Results", page 6

Test strain	<i>Enterococcus hirae</i> DSM3320 ATCC10541
Initial cell count inoculum / cm <sup>2</sup>	1.25 x 10 <sup>4</sup>
Initials of the editor	JJ
Measurement ended on	May-09-2019

Work Order	3332
Setup-Code	190508-10290-2801-01

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### Comments on test objects

NONE

### Interpretation of the results based on the measurements

NONE

**Editor:** Mrs. Jovanovic \_\_\_\_\_

**Crosschecked:** Mr. Mannala\_\_\_\_\_

### References

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