

Work Order	4101.4
Setup-Code	210907-1298-2180-01



Test Report

ASTM E-2180

Standard Method for Determining the Activity of Incorporated Antimicrobial Agent(s) in Polymeric or Hydrophobic Material

Test Object:

*Bacoban DL after artificial aging (12 months real-time)
versus Candida albicans DSM5817 ATCC10259*

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Report on Findings

Client: ROPIMEX R. OPEL GmbH
Address: Bildstocker Straße 12-14
66538 Neunkirchen

Work order no.: 4101.4

Test object: Bacoban DL after artificial aging (12 months real-time) versus
Candida albicans DSM5817 ATCC10259

Sample description: Bacoban DL coated leneta foil

Date of receipt of sample: 05 July 2021

Type of test: ASTM E-2180-07: Standard Method for Determining the Activity of
Incorporated Antimicrobial Agent(s) in Polymeric or Hydrophobic
Material

Test Germ: *Candida albicans* DSM5817 ATCC10259

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstrasse 46a
90411 Nuremberg, Germany

Setup-Code: 210907-1298-2180-01

Sample material: Leneta foil

No. of pages in report: 6

Report on findings to the client: **Place and date of preparation:** Nuremberg, 13 September 2021
Recipient: ROPIMEX R. OPEL GmbH

Approved:


Dr. Sabine Krause, Laboratory Manager
QualityLabs BT GmbH

Work Order	4101.4
Setup-Code	210907-1298-2180-01

Declaration on Quality Assurance

This investigation was performed and supervised according to the standard operating procedure "SOP for ASTM E-2180-07" 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 ASTM E-2180-07.

During the test, a thin film of agar-slurry containing the bacteria (2.5×10^6 / Inoculum) is applied directly to the test sample (3 cm x 3 cm). Immediately after inoculation, the bacteria from the reference sample are separated from the sample 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 film of agar-slurry in a damp environment at 37°C. After a minimum of 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).

Assessment of antimicrobial activity

A germ reduction of $\geq 99.9\%$ of the antimicrobial sample in comparison to the respective reference is used as assessment criterion to pass the antimicrobial test.

Germ reduction [%]	Antibacterial activity
< 99.9%	No sufficient antimicrobial activity
$\geq 99.9\%$	Sufficient antimicrobial activity

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References to deviations, preincubations, special test conditions

Samples were artificially aged and therefore incubated at 50°C for 56 days (corresponds to 12 months real-time aging).

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Test Results

No.	Sample Name	Sample Code	t_0 (cell count / inoculum)				CV [%]	t_{24} (cell count / inoculum)				CV [%]	Reduction [%]
1	Leneta (reference)	12980309210005	2.9×10^6	2.9×10^6	3.2×10^6	8.2×10^6	5.9	8.0×10^6	7.4×10^6			5.0	Reference
2	Leneta coated with Bacoban DL (12 months aged)	12980309210006				8.0×10^2		1.6×10^3	4.0×10^2			-	> 99.9

*see "Interpretation of Results", page 6

Test strain	<i>Candida albicans</i> DSM5817 ATCC10259
Initial cell count / inoculum	2.5×10^6 / 400 μ l
Initials of the editor	JD
Measurement ended on	13 September 2021

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Comments on test objects

NONE

Interpretation of the results based on the measurements

The sample **Leneta coated with Bacoban DL (12 months aged)** showed sufficient antibacterial activity against the test strain *Candida albicans* DSM5817 ATCC10259 compared to the reference sample.

Editor: J. Dittmann JD

Crosschecked: C. Görgey CG

References

ASTM E-2180-07: Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials

ASTM E-1054-08: Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents