

Work Order	559
Measurement	20081210-R06-01-53_Rev_3



Test Report

QualiScreen

Screening of Antimicrobial Efficacy of

Material Surfaces

Test Object:

TitanShield-Beschichtung TS S40-06

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Report on Findings

Client: EcoWays Umwelt Innovationen GmbH
Address: WelldorferStr.12
52428 Jülich

Work order name: 559

Test object: TitanShield-Beschichtung TS S40-06

Sample description: ceramic

Date of receipt of sample: Dec-08-2008

Type of test: QualiScreen: Assay for determining the antimicrobial efficacy of material surfaces against *Staphylococcus epidermidis* DSM 18857

Test laboratory: QualityLabs BT GmbH

Address: Neumeyerstraße 46a
90411 Nuremberg, Germany

Measurement: 20081210-R06-01-53

Sample material: ceramic

Number of pages in report: 5

Report on findings to the client: **Place and date of preparation:** Nuremberg, Jan-23-2009
Recipient: EcoWays Umwelt Innovationen GmbH

Laboratory Director:

Harald Gerauer, Laboratory Director
QualityLabs BT GmbH

Released:

Reiner Hommel, PhD, Managing Director
QualityLabs BT GmbH

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Declaration on Quality Assurance

This investigation was performed and supervised in the style of the standard operating procedure "Assay on the Determination of Antimicrobial Efficacy of Material Surfaces against *Staphylococcus epidermidis*" (SOP 3.2 of 2008-08-05) by QualityLabs BT GmbH. The laboratory and process are continually monitored by independent, external authorities, as well as by internal audits.

Compliance with Regulations

The test was performed according to the regulations of DIN EN ISO/IEC 17025 for testing and calibration laboratories. The quality and integrity of the investigation were not jeopardised at any time.

Laboratory Director:

Harald Gerauer, Laboratory Director
QualityLabs BT GmbH

Test Description

The test objects are incubated with cells of the test strain. Loose cells are removed through defined wash steps. The material being tested is incubated a defined length of time to determine its effect on the proliferation (growth) of bacteria on the object's surface. For non-antimicrobial surfaces, the adhering bacteria continue to divide on the surface of the material and release daughter cells into the surrounding liquid.

Antimicrobial materials affect bacterial growth to different degrees and can even completely prevent cell division.

Because of the number of these released cells is very low after the incubation period, a measurable signal that can be detected by an instrument must be generated through the use of appropriate microbiological methods.

Antimicrobial efficacy is always measured in comparison to a non-antimicrobial blank sample. Clients provide the blank sample, which is identical to the test object in all aspects except that it is free of antimicrobial additives. Internal controls that are present on all microtitre plate assays serve as permanent monitors of the measuring process.

The measurement cannot be evaluated if the blank sample has a higher antimicrobial effect than the test object with antimicrobial agent.

For the QualiScreen test, a material is regarded antimicrobial only if it inhibits the formation of at least 99.9% of the daughter cells during the observation period in comparison to the blank sample.

For QualiScreen, all 4 test objects must test as antimicrobial to obtain the designation 'antimicrobial'.

Measurements that are performed with different strains or species cannot be directly compared with one another.

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References to deviations, preincubations, special test conditions

All samples were irradiated for 1 hour with an UV-lamp before test start.

The following samples were tested one-sidedly:

Keramikfliese, Nullprobe

Keramikfliese, beschichtet mit TitanShield TS S40-06

Comments on test objects

NONE

Interpretation of the results based on the measurements

NONE

Editor: Mr Nagengast _____

Crosschecked: Mr. Konradt _____

References

Bechert et al. (2000)
„ A new method for screening anti-infective biomaterials“
Nature Medicine 6(9): 1053-1056

Alt et al. (2004)
“An in vitro assessment of the antibacterial properties and cytotoxicity of nanoparticulate silver bone cement.”
Biomaterials, 25(18):4383-91

Alt et al. (2004)
“In vitro testing of antimicrobial activity of bone cement.”
Antimicrob Agents Chemother. 48(11):4084-8