

Certificate of Analysis

Certificate of Analysis ID:

1054580500_VM876358_EN

Producer and client:

Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany

Test laboratory:

Merck KGaA Qualitätskontrolle für mikrobiologische Produkte

Frankfurter Str. 250, 64293 Darmstadt, Germany

Sample identification:

GranuCult®

Tryptic Soy Agar acc. EP, USP, JP, ISO and FDA-BAM

Ordering number:

1.05458.0500

Lot number:

VM876358

Accreditation:

The test laboratory of Merck KGaA is accredited by the German accreditation authority DAkkS as registered test laboratory D-PL-15185-01-00 according to DIN EN ISO/IEC 17025 for the performance testing of media for microbiology according to DIN EN ISO 11133:2014.

(DAKKS Deutsche Akkreditierungsstelle D-PL-15185-01-00

Test method:

Performance testing of solid culture media:

Quantitative method (spiral plater)

Date of analysis:

2019/04/03

Date of release:

2019/04/09

Minimum shelf life:

2024/03/18

Composition (g/l):

Pancreatic digest of casein 15.0; Papaic digest of soya bean 5.0;

Sodium chloride 5.0; Agar agar 15.0.

Preparation & sterilization:

Dissolve 40.0 g in 1 liter of purified water. Heat in boiling water and agitate frequently until completely dissolved. Autoclave (15 minutes at

121°C).

Application:

For the isolation and cultivation of a wide range of microorganisms from

different material.

Storage:

Store at +15 °C to +25 °C, dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light).

The reported results refer exclusively to the specified medium, see Certificate of Analysis ID.



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Physical parameters

Specification

Lot value

Appearance (clarity):

clear

clear

Appearance (color):

yellowish-brown

yellowish-brown

pH-value (25 °C):

7.1 - 7.5

7.3

Solidification behaviour (2 h at 45 °C) liquid

liquid

liquid

Stability test (color and hemolysis)

non hemolytic

non hemolytic

Microbiological Performance

Quantitative method for solid media (spiral plater)

Test strain	Specification	Reference CFU	Test CFU	Recovery rate
Escherichia coli ATCC® 8739 [WDCM 00012]	≥ 70 %	201	180	90 %
Escherichia coli ATCC® 25922 [WDCM 00013]	≥ 70 %	246	302	123 %
Bacillus cereus ATCC® 11778 [WDCM 00001]	≥ 70 %	286	263	92 %
Listeria monocytogenes ATCC® 13932 [WDCM 00021]	≥ 70 %	96	88	92 %
Staphylococcus aureus ATCC® 25923 [WDCM 00034]	≥ 70 %	258	266	103 %

Incubation:

24 \pm 3 hours at 37 \pm 1 °C aerobic

Reference medium:

Tryptic Soy Agar

A recovery rate of 70 % is equivalent to a productivity rate of 0.7.

The indicated colony counts result from the sum of a triple determination.

All test methods listed above are according to DIN EN ISO

11133:2014.



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Test strain	Specification	Reference	Test	Recovery rate
, 550 50 600	•	10 - 100 CFU	CFU	
Staphylococcus aureus* ATCC® 6538 [WDCM 00032]	≥ 70 %	35	33	94 %
Bacillus subtilis* ATCC® 6633 [WDCM 00003]	≥ 70 %	26	31	119 %
Escherichia coli* ATCC® 8739 [WDCM 00012]	≥ 70 %	77	66	86 %
Pseudomonas aeruginosa* ATCC® 9027 [WDCM 00026]	≥ 70°%	66	67	102 %
Candida albicans* ATCC® 10231 [WDCM 00054]	≥ 70 %	50	60	120 %
Aspergillus brasiliensis* ATCC® 16404 [WDCM 00053]	≥ 50 %	54	47	87 %

Incubation:

24 hours at 30 – 35 °C aerobic, C.albicans and A.brasiliensis up to 5 $\,$

days.

Reference medium:

Blood Agar and SABOURAUD dextrose agar for C.albicans / A.brasiliensis

Parameters marked with an asterisk have not been tested by an accredited method.

Signature:

Dr. Stefanie Fischer

Head of Quality Control Microbiology