

Certificate of Analysis



Certificate of Analysis ID: 1054580500_VM1110458_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® prime
Tryptic Soy Agar acc. EP, USP, JP, ISO and FDA-BAM

Ordering number: 1.05458.0500

Lot number: VM1110458

Sample ID: 201545573

Accreditation:



Test method: DIN EN ISO 11133:2020
Performance testing of solid culture media:
Quantitative method (spiral plater)

Date of analysis: 2024/12/02

Date of release: 2024/12/03

Minimum shelf life: 2029/11/30

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	7.4
Solidification behaviour (2 h at 45 °C)	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 %	192	210	109 %
Escherichia coli ATCC® 25922 [WDCM 00013]	≥ 70 %	294	298	103 %
Bacillus cereus ATCC® 11778 [WDCM 00001]	≥ 70 %	119	128	108 %
Listeria monocytogenes ATCC® 13932 [WDCM 00021]	≥ 70 %	212	220	104 %
Staphylococcus aureus ATCC® 25923 [WDCM 00034]	≥ 70 %	214	207	97 %

Incubation: 24 ± 3 hours at 37 ± 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.



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Test strain	Specification	Reference 10 – 100 CFU	Test CFU	Recovery rate
Staphylococcus aureus* ATCC® 6538 [WDCM 00032]	≥ 70 %	39	34	87 %
Bacillus subtilis* ATCC® 6633 [WDCM 00003]	≥ 70 %	50	54	108 %
Escherichia coli* ATCC® 8739 [WDCM 00012]	≥ 70 %	80	75	94 %
Pseudomonas aeruginosa* ATCC® 9027 [WDCM 00026]	≥ 70 %	75	70	93 %
Candida albicans* ATCC® 10231 [WDCM 00054]	≥ 70 %	35	37	106 %
Aspergillus brasiliensis* ATCC® 16404 [WDCM 00053]	≥ 50 %	31	25	81 %

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.

Release: Culture medium released by Approving Officer or delegate LS-SC-PCDQS6

Dr. Lukas Mechler

Responsible Manager of LS-SC-PCDQS6 (Test Laboratory D-PL-15185-01-00)

Certificate of analysis revision history:

Certificate version	Date	Status	Reason for version
01	2024/12/03	effective	Initial version