OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

TRYPTONE SOYA AGAR CM0131

TRYPTONE SOYA AGAR **CM0131**

(Casein soya bean digest agar)†
† EP, USP, JP, BP

Typical Formula*

Pancreatic digest of casein	grams per litre	15.0
Enzymatic** digest of soya bean		5.0
Sodium chloride		5.0
Agar		15.0

** contains papain

* adjusted as required to meet performance standards

Directions

Suspend 40g in 1 litre of water (purified, as required). Bring to the boil to dissolve completely. Sterilize by autoclaving at 121°C for 15 minutes. Mix well and pour into sterile Petri dishes.

Physical Characteristics

Straw, free-flowing powder
Colour on reconstitution - straw 1-2
Moisture level - less than or equal to 7%
pH 7.3 ± 0.2 at 25°C
Clarity - clear
Gel strength - firm, comparable to 15.0g/litre of agar

The medium is tested for compatibility using 7% v/v oxalated horse blood, defibrinated horse blood or defibrinated sheep blood. There shall be no evidence of lysis or darkening, after incubation at 37°C, 25°C and 4°C for 72 hours.

Microbiological Tests using Optimum Inoculum Dilution

Control Medium: Tryptone Soya Agar

Plain plates

Reactions after incubation at 30-35°C for 18-24 hours

Medium is challenged with 10-100 colony-forming units

Streptococcus pyogenes	ATCC®19615	0.25-0.5mm pale straw colonies

Streptococcus viridans	NCTC1080	0.25-0.5mm pale straw colonies
Staphylococcus aureus	ATCC®9144	0.5-1mm straw colonies
Staphylococcus epidermidis	ATCC®12228	1-2mm white/grey colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Enriched with 7% v/v horse blood

Reactions after incubation at 37°C for 24 hours
Medium is challenged with 10-100 colony-forming units

Streptococcus pyogenes	ATCC®19615	0.25-0.5mm pale straw colonies, β haemolysis
Streptococcus viridans	NCTC1080	0.5-1mm grey/green colonies, α haemolysis
Streptococcus pneumoniae	ATCC®6305	0.5-1mm grey/green colonies, α haemolysis

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after incubation at 37°C for 48 hours under microaerophilic conditions

Haemophilus influenzae	ATCC® 19418	Pinpoint-0.5mm colourless colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Zones of growth/no growth surrounding X, V and X+V factor discs (DD0003, DD0004 and DD0005) when plain plates are inoculated with the following organisms and incubated at 37°C for 18 hours:

		X	V	X+V
Haemophilus influenzae	ATCC®9334	0	0	≥ 15mm
Haemophilus influenzae	ATCC®19418	0	0	≥ 15mm
Haemophilus influenzae	ATCC®49247	0	0	≥ 15mm
Haemophilus parainfluenzae	ATCC®33392	0	≥ 20mm	≥ 20mm

Zones of inhibition with Bacitracin discs (DD0002) shall be 10-20mm when 7% v/v horse blood plates are inoculated with *Streptococcus pyogenes* ATCC® 19615 and incubated at 37°C for 18 hours.

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Testing performed in accordance with ISO11133:2014

Plain plates

Reactions after incubation at 30 ± 2°C for 24 ± 2 hours

Medium is challenged with 50-120 colony-forming units

Bacillus cereus	ATCC®11778	WDCM00001	3-5mm irregular, straw colonies
Bacillus subtilis	ATCC®6633	WDCM00003	2-4mm irregular, straw colonies
Escherichia coli	ATCC®8739	WDCM00012	1-3mm cream colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after incubation at 36 ± 2°C for 20 ± 2 hours

Medium is challenged with 50-120 colony-forming units

Escherichia coli	ATCC®25922	WDCM00013	1-3mm cream colonies
Escherichia coli	ATCC®11775	WDCM00090	1-3mm cream colonies
Escherichia coli	NCTC13167	WDCM00179	1-3mm cream colonies
Pseudomonas aeruginosa	ATCC®10145	WDCM00024	1-4mm straw colonies
Enterococcus faecalis	ATCC®29212	WDCM00087	0.5-2mm straw colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after incubation at 37 ± 2°C for 24 ± 2 hours

Medium is challenged with 50-120 colony-forming units

Staphylococcus aureus	ATCC®25923	WDCM00034	0.5-1mm straw colonies
Listeria monocytogenes	ATCC®13932	WDCM00021	0.25-2mm straw colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after incubation at 44 ± 2°C for 21 ± 3 hours

Medium is challenged with 50-120 colony-forming units

Escherichia coli	ATCC®8739	WDCM00012	1-3mm cream colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after anaerobic incubation at 44 ± 2°C for 21 ± 3 hours

Medium is challenged with 50-120 colony-forming units

Clostridium perfringens	ATCC®13124	WDCM00007	1-2mm straw colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Testing performed in accordance with current CLSI M22 A

Enriched with 5% Sheep Blood

Reactions after incubation at 35 ± 2°C for 21 ± 3 hours

Medium is challenged with 1E+02 to 1E+04 colony-forming units

Streptococcus pyogenes	ATCC®19615	0.5-1mm pale straw colonies, β haemolysis
Streptococcus pneumoniae	ATCC®6305	0.5-2mm grey/green colonies, α haemolysis
Staphylococcus aureus	ATCC®25923	1-2mm white/grey colonies
Escherichia coli	ATCC®25922	1-2mm straw colonies

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Testing performed in accordance with current USP/EP/BP/JP

Plain plates

Reactions after incubation at 30-35°C for 24 hours

Medium is challenged with 10-100 colony-forming units

Staphylococcus aureus	ATCC®6538	0.5-1mm straw colonies
Escherichia coli	ATCC®8739	1-3mm cream colonies
Bacillus subtilis	ATCC®6633	2-4mm irregular, straw colonies
Pseudomonas aeruginosa	ATCC®9027	1-4mm straw colonies
Salmonella typhimurium	ATCC®14028	1-3mm straw colonies
Salmonella abony	NCTC6017	1-3mm straw colonies

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

Reactions after incubation at 30-35°C for 5 days

Medium is challenged with 10-100 colony-forming units

Candida albicans	ATCC®10231	1-3mm cream colonies
Aspergillus brasiliensis	ATCC®16404	Greater than 10mm colonies, white mycelia, with/without black spores

A satisfactory result is represented by recovery of positive strains equal to or greater than 70% of the control medium.

The Microbiological Quality Control of this product complies with the following pharmacopoeia;

1. European Pharmacopoeia: Current version.
   2.6.12 Microbiological Examination of Non-Sterile Products: Harmonised Method: Microbial Enumeration tests
   2.6.13 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms. B. Harmonised Method
2. United States Pharmacopoeia: Current version.
   61 Microbiological Examination of Non-Sterile Products: Microbial Enumeration tests.
   62 Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms
3. Japanese Pharmacopoeia: Current version.

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Revision History

Section / Step	Description of Change	Reason for Change	Reference
Entire document/ Microbiological Characteristics	Update to current format. Removal of duplicate results and obsolete statements/ Change *Haemophilus influenzae* from ATCC9344 to 9334. Change 44°C incubation time from 21 ± 2 hours to ± 3 hours.	Minor - Implementation of IVDR (2017746)	MOC-2022-0167