


| | | |
|---|-------------------------------|------------------|
|  | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 1 of 6 |
| 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

| | | |
|---|-------------------------------|------------------|
| ThermoFisher SCIENTIFIC | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 2 of 6 |
| OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION | | |
| TRYPTONE SOYA AGAR CM0131 | | |

| | | |
|-----------------------------------|------------|--------------------------------|
| <i>Streptococcus viridans</i> | NCTC1080 | 0.25-0.5mm pale straw colonies |
| <i>Staphylococcus aureus</i> | ATCC®9144 | 0.5-1mm straw colonies |
| <i>Staphylococcus epidermidis</i> | 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

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


| | | |
|-------------------------------|-------------|------------------------------------|
| <i>Haemophilus influenzae</i> | 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 |
|-----------------------------------|------------|---|--------|--------|
| <i>Haemophilus influenzae</i> | ATCC®9334 | 0 | 0 | ≥ 15mm |
| <i>Haemophilus influenzae</i> | ATCC®19418 | 0 | 0 | ≥ 15mm |
| <i>Haemophilus influenzae</i> | ATCC®49247 | 0 | 0 | ≥ 15mm |
| <i>Haemophilus parainfluenzae</i> | 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.

| | | |
|---|-------------------------------|------------------|
|  | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 3 of 6 |
| OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION | | |
| TRYPTONE SOYA AGAR CM0131 | | |

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

| | | | |
|--------------------------|------------|-----------|---------------------------------|
| <i>Bacillus cereus</i> | ATCC®11778 | WDCM00001 | 3-5mm irregular, straw colonies |
| <i>Bacillus subtilis</i> | ATCC®6633 | WDCM00003 | 2-4mm irregular, straw colonies |
| <i>Escherichia coli</i> | 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

| | | | |
|-------------------------------|------------|-----------|------------------------|
| <i>Escherichia coli</i> | ATCC®25922 | WDCM00013 | 1-3mm cream colonies |
| <i>Escherichia coli</i> | ATCC®11775 | WDCM00090 | 1-3mm cream colonies |
| <i>Escherichia coli</i> | NCTC13167 | WDCM00179 | 1-3mm cream colonies |
| <i>Pseudomonas aeruginosa</i> | ATCC®10145 | WDCM00024 | 1-4mm straw colonies |
| <i>Enterococcus faecalis</i> | 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

| | | | |
|-------------------------------|------------|-----------|-------------------------|
| <i>Staphylococcus aureus</i> | ATCC®25923 | WDCM00034 | 0.5-1mm straw colonies |
| <i>Listeria monocytogenes</i> | 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.

| | | |
|---|-------------------------------|------------------|
|  | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 4 of 6 |
| OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION | | |
| TRYPTONE SOYA AGAR CM0131 | | |

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

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

| | | |
|---|-------------------------------|------------------|
|  | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 5 of 6 |
| OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION | | |
| TRYPTONE SOYA AGAR CM0131 | | |

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

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

| | | |
|---------------------------------|-------------|--|
| <i>Candida albicans</i> | ATCC® 10231 | 1-3mm cream colonies |
| <i>Aspergillus brasiliensis</i> | 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.

| | | |
|---|-------------------------------|------------------|
|  | Document Owner Department: QC | MBD-BT-SPEC-0094 |
| | | Page 6 of 6 |
| OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION | | |
| TRYPTONE SOYA AGAR CM0131 | | |

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 <i>Haemophilus influenzae</i> from ATCC9344 to 9334. Change 44°C incubation time from 21 ± 2 hours to ± 3 hours. | Minor - Implementation of IVDR (2017746) | MOC-2022-0167 |