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Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated)*

REF **CM0739B, CM0739R and CM0739T** **EN**

*These Instructions for Use (IFU) are intended to be read in conjunction with the IFU for Oxoid Limited's CCDA Selective Supplements (product codes: SR0155E, SR0155H).

Intended Use

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R or CM0739T)) when supplemented with CCDA Selective Supplements (SR0155E or SR0155H), is a blood-free selective medium intended for the isolation of *Campylobacter* species from faecal samples.

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated), with CCDA Selective Supplement added, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.

The device is for professional use only, is not automated, nor is it a companion diagnostic.

The device can also be used to test non-clinical samples, such as food samples.

Summary and Explanation

Campylobacter species are Gram-negative rods in appearance. Two of the most medically relevant *Campylobacter* species isolated from human samples are *Campylobacter coli* and *Campylobacter jejuni*.[1] The symptoms of *Campylobacter* spp. infections are characterised by vomiting, nausea, body aches, abdominal pain and in some cases bloody diarrhoea.[2] In acute stages, the symptoms of *Campylobacter* infections mimic ulcerative colitis and appendicitis.[3] Long term complications of Campylobacter infections include arthritis, Guillain Barr Syndrome (GBS) and Irritable Bowel Syndrome (IBS).

The implications of *Campylobacter* infections can vary from person to person.[4] In most cases, pregnant ladies, patients with AIDS, other blood disorders like thalassemia, patients undergoing chemotherapy and those with a weakened immune system are at high risk.[5] Moreover, the resistance shown by the *Campylobacter* species to fluoroquinolones like ciprofloxacin complicates treatment.[6] CCDA Selective Medium (PO0119A), and Campylobacter Blood-Free Selective Agar Base (Dehydrated) (CM0739B/R/T) with CCDA Selective Supplements (SR0155E/H) are therefore a key tool for the clinician to support the isolation of *Campylobacter* species from faecal samples.

Principle of Method

The formulation of Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R and CM0739T) contains a nutrient broth comprised of peptone and Lab Lemco powder which with casein hydrolysate are sources of nitrogen and other nutrients. Ferrous sulphate, sodium pyruvate and charcoal replace the blood used in other formulations of campylobacter culture media. Charcoal acts as an adsorbent for toxic compounds. Sodium desoxycholate is added to suppress the growth of Gram-positive organisms. CCDA Selective Supplements (SR0155E and SR0155H) added to DCM contains cefoperazone, a cephalosporin that acts as a broad-spectrum antimicrobial with activity against a wide range of microorganism including Enterobacteriaceae and *Pseudomonas* species. Amphotericin B is added to inhibit fungi, this is required when medium is incubated at 37°C to prevent overgrowth of yeasts.

Typical Formula

	grams per litre
Nutrient Broth No. 2	25.0
Activated carbon	4.0
Casein hydrolysate	3.0
Sodium desoxycholate	1.0
Iron (II) sulphate	0.25
Sodium pyruvate	0.25
Agar	12.0

Materials Provided

- CM0739B: 500g pot
- CM0739R: 2.5kg pot
- CM0739T: 5kg pot

Materials Required but Not Supplied

- Inoculating loops, swabs, collection containers
- Incubators
- Quality control organisms
- Selective supplements (SR0155E or SR0155H)
- Petri Dishes

Storage

Store dehydrated media in its original packaging between 10°C and 30°C. Keep out of direct sunlight. Keep away from moisture.

Once reconstituted, store media between 2°C and 12°C.

Warnings and Precautions

- For in vitro diagnostic use only.
- For professional use only.
- Inspect the product packaging before first use.
- Do not use the product if there is any visible damage to the packaging.
- Do not use the product beyond the stated expiry date.
- Do not use the device if signs of contamination are present.
- Do not use the device if the colour has changed or there are other signs of deterioration.
- It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations. Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product (www.thermofisher.com).

Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

Materials of Animal Origin

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R, CM0739T) contains peptone manufactured from porcine, bovine and microbial raw materials.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product (www.thermofisher.com).

Specimen Collection, Handling and Storage

Specimen should be collected and handled following local the recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI) ID 23 and Q 5.

Procedure

- Suspend 22.75g in 500ml of distilled water.
- Bring to the boil to dissolve completely.
- Sterilize by autoclaving at 121°C for 15 minutes.
- Cool to 50°C.
  Aseptically add the contents of 1 vial of CCDA Selective Supplement (SR0155E or SR0155H) reconstituted as directed.
- Mix well and dispense into sterile Petri dishes.

Interpretation

Campylobacter spp. will show as 0.5 - 2mm grey colonies. Identification is presumptive and should be confirmed.

Quality Control

It is the responsibility of the user to perform Quality Control testing taking into account the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature etc.).

The performance of this medium can be verified by testing the following reference strains.

Incubation Conditions:48 h @ 37° ± 2°C microaerophilic

Positive Controls Colony count is ≥ 50% of the control medium count Inoculum level 10 – 100 cfu	
Campylobacter jejuni ATCC® 33560™	0.5-2.0 mm grey colonies
A satisfactory result is represented by growth in accordance with the specification. Inoculum level 10^4 – 10^6 cfu	
Campylobacter lari ATCC® 35221™	0.5-2.0 mm grey colonies
Negative Controls	
Escherichia coli ATCC® 25922™	No growth
Escherichia coli ATCC® 8739™	No growth
Staphylococcus aureus ATCC® 25923™	No growth

Limitations

Identifications are presumptive and should be confirmed.

Plates of C.C.D.A should not be overdried. Non target microorganisms may grow on this medium if they are resistant to the antimicrobials present. This includes cefaperazone-resistant Enterobacteriaceae and Pseudomonas species. *Campylobacter* species vary in their sensitivity to antimicrobial agents and therefore may not grow on this medium. Incubation at 42°C may prevent the growth of some *Campylobacter* species such as *C. jejuni* subspecies doylel and *C. fetus* sub species intestinalis.

Performance Characteristics

Accuracy has been demonstrated through review of the QC data. Correct detection of *Campylobacter species* is confirmed by the inclusion of a well-characterised isolate in the QC processes performed as part of the manufacture of each batch of the device.

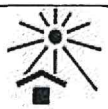
The precision of Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R, CM0739T) was demonstrated by an overall pass rate of 100% over six months of testing (July 2021 - January 2022). This shows that the performance is reproducible.

Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739) device is tested in-house as part of the QC process since the products were launched in 1996. For target organisms, when using 10-100 cfu inoculum of Campylobacter jejuni ATCC® 33560 and and 104-106 cfu Campylobacter lari ATCC® 35221 and incubating the device at 37 ± 2°C for 48 hours, the user can recover organisms with colony size and morphology as listed in this document. For non-target organisms, when using 104-106 cfu inoculum of Escherichia coli ATCC® 25922, Escherichia coli ATCC®8739 and Staphylococcus aureus ATCC® 25923 incubating the device at 37 ± 2°C for 48 hours, the user can recover organisms with colony size and morphology as listed in this document.

Bibliography

1. Public Health England.2014 'Identification of Campylobacter species ID_23i3.1 I. https://www.gov.uk/government/publications/smi -id-23-identification-of-campylobacter-species.
2. Skirrow M.B. (1977) *Brit. Med. Jour.* 2, 9-11.
3. Akar, M., Aydin, F., Yurci, M. A., Abay, S., Ateş, İ., & Deniz, K. (2018). The possible relationship between Campylobacter spp./Arcobacter spp. and patients with ulcerative colitis. European *Journal of Gastroenterology & Hepatology*, 30(5), 531–538.
4. Ramos, A. P., Leonhard, S. E., Halstead, S. K., Cuba, M. A., Castañeda, C. C., Dioses, J. A., Tipismana, M. A., Abanto, J. T., Llanos, A., & Gourlay, D. (2021). Guillain-Barré syndrome outbreak in Peru 2019 associated with Campylobacter jejuni infection. *Neurology- Neuroimmunology Neuroinflammation*, 8(2).
5. Centers for Disease Control and Prevention. 2019. '*Campylobacter* (Campylobacteriosis). https://www.cdc.gov/campylobacter/technical.ht ml
6. Rodrigues, J., Cha, W., Mosci, R. E., Mukherjee, S., Newton, D. W., Lephart, P., Salimnia, H., Khalife, W. T., Rudrik, J. T., & Manning, S. D. (2021). Epidemiologic associations vary between tetracycline and fluoroquinolone resistant Campylobacter jejuni infections. *Frontiers in Public Healt*h, 9, 820.

Symbol Legend

Symbol	Definition
	Catalogue number
	In Vitro Diagnostic Medical Device
	Batch code
	Temperature limitation (storage temp.)
	Use by (expiration date) YYYY- MM
	Keep away from sunlight
	Consult Instructions for Use
	Do not use if packaging damaged
	Manufacturer
	Authorized representative in the European Community

CE	European Conformity Assessment
UK CA	UK Conformity Assessment
UDI	Unique device identifier
	Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union
Made in the United Kingdom	Made in the United Kingdom

ATCC Licensed Derivative

Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, UK

CE UK CA

For technical assistance please contact your local distributor.

Revision information

Version	Date of issue and modifications introduced
4.0	2024-10-10 Addition of non-clincial claims Minor formatting updates Updated UK SMIs

www.thermofisher.com

CCDA Selective Supplement*

REF **SR0155E, SR0155H** EN

*This instructions for use (IFU) document is intended to be read in conjunction with the IFU for Oxoid Limited's Campylobacter Blood-Free Selective Agar Base (product codes: CM0739B, CM0739R and CM0739T)

Intended Use

CCDA Selective Supplement (SR0155E, SR0155H) are selective supplements intended to be used with Campylobacter Blood-Free Selective Agar Base (Dehydrated) (CM0739B, CM0739R, or CM0739T) for the isolation of *Campylobacter* species from faecal samples.

CCDA Selective Supplements, when added to CCDA Campylobacter Blood-Free Selective Agar Base, are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.

The devices are for professional use only, are not automated, and nor are they companion diagnostics.

Summary and Explanation

Campylobacter species are Gram-negative rods in appearance. Two of the most medically relevant *Campylobacter* species isolated from human samples are *Campylobacter coli* and *Campylobacter jejuni*.[1] The symptoms of *Campylobacter* spp. infections are characterised by vomiting, nausea, body aches, abdominal pain and in some cases bloody diarrhoea.[2] In acute stages, the symptoms of *Campylobacter* infections mimic ulcerative colitis and appendicitis.[3] Long term complications of Campylobacter infections include arthritis, Guillain Barr Syndrome (GBS) and Irritable Bowel Syndrome (IBS).

The implications of *Campylobacter* infections can vary from person to person.[4] In most cases, pregnant ladies, patients with AIDS, other blood disorders like thalassemia, patients undergoing chemotherapy and those with a weakened immune system are at high risk.[5] Moreover, the resistance shown by the *Campylobacter* species to fluoroquinolones like ciprofloxacin complicates treatment.[6] Campylobacter Blood-Free Selective Agar Base (Dehydrated) (CM0739B/R/T) with CCDA Selective Supplements (SR0155E/H) are therefore a key tool for the clinician to support the isolation of *Campylobacter* species from faecal samples.

Principle of Method

CCDA Selective Supplements (SR0155E and SR0155H) added to DCM contains cefoperazone, a cephalosporin that acts as a broad-spectrum antimicrobial with activity against a wide range of microorganism including Enterobacteriaceae and *Pseudomonas* species. Amphotericin B is added to inhibit fungi, this is required when medium is incubated at 37°C to prevent overgrowth of yeasts.

Typical Formula

	Milligrams per 500ml
Cefoperazone	16.0 mg
Amphotericin B	5.0 mg

Materials Provided

SR0155E: 10 vials - each supplements 500 ml of medium
SR0155H: 10 vials - each supplements 2 L of medium

Materials Required but Not Supplied

- Dehydrated culture media base CM0739B/R/T
- Inoculating loops
- Swabs
- Collection containers
- Incubators/ Anaerojar (AG0025A, AB0035A, AB0025A) / CampyGen (CN0025A, CN0035A)
- Quality control organisms

Storage

- Store product in its original packaging between 2°C and 8°C.
- Keep container tightly closed.
- The product may be used until the expiry date stated on the label.
- Protect from moisture.
- Store away from light.
- Allow reconstituted product to equilibrate to room temperature before use.

Warnings and Precautions

Danger:

- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause an allergic skin reaction.
- Wear protective gloves/protective clothing/eye protection/face protection.
- IF ON SKIN: Wash with plenty of soap and water.
- If skin irritation or rash occurs: Get medical advice/attention.
- In case of inadequate ventilation wear respiratory protection.
- IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
- If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
- Causes serious eye irritation.

- DO NOT USE SUPPLEMENTS IF YOU ARE PREGNANT OR CONTEMPLATING PREGNANCY.
- Each vial is for single use. Do not re-use.
- For in vitro diagnostic use only.
- For professional use only.
- Inspect the product packaging before first use.
- Do not use the product if there is any visible damage to the packaging and vial.
- Do not use the product beyond the stated expiry date.
- Do not use the device if signs of contamination are present.
- It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations. Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product (www.thermofisher.com).

Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

Specimen Collection, Handling and Storage

Specimen should be collected and handled following local the recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI) Q5.

Procedure

- Allow supplement to equilibrate to room temperature before use.
- Aseptically add 2ml of sterile distilled water to 1 vial and mix gently to dissolve completely. Avoid frothing.
- SR0155E: Add the vial contents to 500ml of sterile Campylobacter Blood-Free Selective Agar Base (CM0739) prepared as directed and cooled to 50°C.
- SR0155H: Add the vial contents to 2l of sterile Campylobacter Blood-Free Selective Agar Base (CM0739) prepared as directed and cooled to 50°C.
- Mix well and pour into sterile Petri dishes.

Bibliography

1. Public Health England.2014 'Identification of Campylobacter species ID_23i3.1 I. https://www.gov.uk/government/publications/smi-id-23-identification-of-campylobacter-species.
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Symbol Legend

Symbol	Definition
REF	Catalogue number
IVD	In Vitro Diagnostic Medical Device
LOT	Batch code
	Temperature limit
	Use-by date
	Keep away from sunlight
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Contains sufficient for <n> tests
	Do not use if packaging damaged and consult instructions for use
	Manufacturer
EC REP	Authorized representative in the European Community/ European Union
CE	European Conformity Assessment
UK CA	UK Conformity Assessment
UDI	Unique device identifier
	Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union
Made in the United Kingdom	Made in the United Kingdom

Oxoid Limited, Wade Road,
Basingstoke, Hampshire, RG24 8PW,
UK

CE UK CA

For technical assistance please contact your local distributor.

Revision information

Version	Date of issue
2.0	2023-08-18

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

EDWARDS MEDIUM (MODIFIED) CM0027

EDWARDS MEDIUM (MODIFIED) **CM0027**

Typical Formula*

'Lab-Lemco' powder	grams per litre	10.0
Peptone		10.0
Aesculin		1.0
Sodium chloride		5.0
Crystal violet		0.0013
Thallous sulphate		0.33
Agar		15.0

*adjusted as required to meet performance standards

Directions

Suspend 41g in 1 litre of distilled water. Bring to the boil to dissolve completely. Sterilize by autoclaving at 115°C for 20 minutes. Cool to 50°C, add 5 to 7% v/v sterile bovine or sheep blood, mix well and pour plates.

Physical Characteristics

Straw, free-flowing powder
Colour on reconstitution – straw/blue hue
Moisture level - less than or equal to 7%
pH - 7.4 ± 0.2 at 25°C
Clarity - clear
Gel strength - firm, comparable to 15.0g/litre of agar

Microbiological Tests Using Optimum Inoculum Dilution

Control Medium: Columbia Blood Agar Base enriched with 5% v/v horse blood

Enriched with 7% v/v sheep blood

Reactions after incubation at 37°C for 18–24 hours

Medium is challenged with 10-100 colony-forming units

Streptococcus agalactiae	ATCC®13813	0.25-1mm blue colonies, no fermentation
Enterococcus faecalis	ATCC®29212	0.25-1mm blue/black colonies with fermentation
Streptococcus pyogenes	ATCC®19615	0.25-0.5mm pale blue colonies, no fermentation

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

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

EDWARDS MEDIUM (MODIFIED) CM0027

Medium is challenged with 1E+04 to 1E+06 colony-forming units

Staphylococcus aureus	ATCC®9144	No growth
Escherichia coli	ATCC®25922	No growth
Staphylococcus epidermidis	ATCC®12228	No growth

Negative strains are inhibited.

Additional challenging strains are employed.

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

EDWARDS MEDIUM (MODIFIED) CM0027

Revision History

Section / Step	Description of Change	Reason for Change	Reference
Entire Document	Update to new document format and correction of typographical/minor errors. Change NCTC6571 to ATCC®9144. Addition of control media and result criteria.	Change control	BT-CC-1924