Certificate of Analysis

PREPARED MICROBIOLOGICAL MEDIA

BURKHOLDERIA CEPACIA AGAR

Catalogue Number	CMS149-10-10
Product Description	Burkholderia Cepacia Agar, 10cm Petri Dish, Package of 10
Lot Number	1248
Date of Manufacture	17 November 2022
Expiry Date	16 January 2023

INTENDED USE

A medium for the selective isolation of *Burkholderia cepacia* from the respiratory secretions of patients with cystic fibrosis and routine testing of non-sterile inorganic salt solutions containing preservatives.

SUMMARY AND EXPLANATION

Burkholderia cepacia (formerly known as *Pseudomonas cepacia*) is a motile aerobic oxidase-positive Gram-negative bacillus commonly found in liquid reservoirs and moist environments. The cells are 0.5 to 1.0mm wide and 5mm in length. It is an important opportunistic pathogen and causes pulmonary infection among individuals with cystic fibrosis (CF). Isolates from CF patients often display multidrug resistance and as many as 20% of colonized individuals will succumb to *Burkholderia cepacia* syndrome, necrotizing pneumonia associated with fever that culminates into a rapid and fatal clinical deterioration[1]. Oxoid's *Burkholderia cepacia* Agar is based on PC Medium originally devised by Gilligan *et al.* where it was shown to be superior for the growth of *Burkholderia cepacia* after 48 hours when compared to MacConkey[2].

Originally isolated from onions, *Burkholderia cepacia* can survive for long periods and multiply in hostile environments such as antiseptic and disinfectant solutions, distilled water, whirlpool baths, nebulizers and commercially packaged urinary catheter kits[3]. An outbreak in Arizona in 1998 due to contaminated alcohol-free mouthwash, was investigated by the Food and Drug Administration (FDA), which suggested an association with the deionisation procedure of the water used to prepare the product[4]. The organism may be present in low numbers in many non-sterile products used in hospitals. It has been isolated from various water sources and can grow in distilled water with a nitrogen source due to its ability to fix carbon dioxide from air[5]. Suction catheters rinsed in acetic acid solution have reduced the incidence of transmission of *Burkholderia cepacia* and other pseudomonads.

The slower-growing *Burkholderia cepacia* can be missed on conventional media such as blood or MacConkey Agar due to overgrowth caused by other faster-growing organisms found in the respiratory tract of CF patients such as mucoid *Klebsiella* species, *Pseudomonas aeruginosa* and *Staphylococcus* species. This may lead to the infection being missed or wrongly diagnosed.

PRINCIPLE

Suspend 18.25g of *Burkholderia cepacia* Agar Base in 500ml of distilled water, mix well, and sterilize by autoclaving at 121°C for 15 minutes. Cool to 50°C and aseptically add the contents of one vial of *Burkholderia cepacia* Selective Supplement SR0189, reconstituted as directed. Mix well and distribute into sterile Petri dishes.

PROCEDURE

The appearance of the medium is slightly turbid with particles and colorless. The pH value is in the range of 7.0-7.4. The medium can be adjusted and/or supplemented according to the performance criteria required.

EXPECTED RESULTS

Take a routine respiratory sample from the patient e.g. sputa, deep pharyngeal swabs, or bronchial washings. Dilute the sample, if necessary, in Ringer's solution to give a 1:2 dilution. Streak onto *Burkholderia cepacia* Medium and incubate at 37°C for 48 to 72 hours.

Examine after 48 hours for sage green colonies and the medium turning from straw-green to bright pink. All colonies should be further identified and confirmed. Re-incubate for a further 24 hours if necessary. Typical colonies of *Burkholderia cepacia* are circular and entire. Colour formation is based on natural pigment expression and colonies vary from grey to sage green, with the medium changing from orange to bright pink.

QUALITY CONTROL

All lot numbers have been tested and are acceptable. Customers can test products using the following quality control organisms. Testing of control organisms should be performed by established laboratory quality control procedures. If aberrant quality control results are noted, sample results should not be reported.

QA Testing:	Result:	Expected:
Characteristics	**Pass**	**Pass**
Sterility	**Pass**	**Pass**
Performance	**Pass**	**Pass**

pH	7.2 ± 0.2 @ 25°C
Appearance	Purple, Clear
Storage Condition	Refrigerate, 2-8°C

Sterility Method	Autoclave
Sterility Test	Pass

(Absence of growth following 72 hours at 30 - 35°C)

Dehydrated medium: Straw pink, free-flowing powder
Prepared medium: Orange-colored gel

Positive control:	Expected results
Burkholderia cepacia ATCC® 25608*	Good growth, grey colonies with bright pink medium. Low numbers of colonies may not produce a color change of the medium.
Burkholderia cepacia ATCC® 25416*	Good growth, sage green colonies with bright pink medium. Low numbers of colonies may not produce a color change of the medium.
Negative control:	
Pseudomonas aeruginosa ATCC® 27853*	Inhibited

ATCC® is a registered trademark of the American Type Culture Collection.

BIBLIOGRAPHY

1- Whitby, P. W. (1998) *Journal of Clinical Microbiology* **36:** 1642-1645 Gilligan, P. H. *et al.* (1985) Journal.
2- Clinical Microbiology 22: No.1 5-8.
3- Geftic, S. G., Heymann, H. and Adair, F. W. (1979) *Applied and Environmental Microbiology* **37:** 505-510
4- Matrician, L. (1998) *Virtual Hospital: Morbidity and Mortality Weekly Report* Volume **47:** No. 43
5- Koneman, E. W. *et al.* (1997) *Color Atlas and Textbook of Diagnostic Microbiology* Fifth Ed.: 269-272

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All our prepared media products are manufactured at our site in RCFFN, University of Manitoba, and tested both at our site and by the Department of Microbiology, University of Manitoba.

The generation of this certificate confirms all sterilization and performance criteria have been achieved.

NOTE: Expiry Date only valid if packs are stored unopened at Ambient Room Temperature not exceeding 25°C.

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