BURKHOLDERIA CEPACIA SELECTIVE AGAR for USP<60>

INTENDED USE

Remel Burkholderia Cepacia Selective Agar for USP <60> is a solid medium recommended for use in qualitative procedures for the selective and differential isolation of *Burkholderia cepacia* complex in products especially those for inhalation use or aqueous preparations for oral, oromucosal, cutaneous or nasal use.

SUMMARY AND EXPLANATION

In 2017, the FDA issued an advisory to drug manufacturers concerning the risk of contamination of non-sterile water-based drug products with microorganisms from the *Burkholderia cepacia* complex (Bcc). This advisory was in response to recent product recalls by several manufacturers due to contamination of their drug products with *B. cepacia* complex. In response, the *U.S. Pharmacopeia* developed a test for *Burkholderia cepacia* complex in nonsterile products¹.

B. cepacia is a gram-negative aerobic bacteria that is widespread and commonly found in soil and water. It is capable of surviving for extended periods of time in hostile environments due to its innate resistance to many antiseptics and antibiotics.

PRINCIPLE

This medium contains yeast extract and casein peptone as nutritive components. Sodium chloride maintains osmotic equilibrium and agar is added as a solidifying agent. Crystal violet, polymyxin B, gentamicin, and vancomycin are selective agents, which inhibit organisms commonly found in respiratory secretions other than *B. cepacia* complex. Sucrose and lactose are carbohydrates for enrichment and differentiation with phenol red as a pH indicator.

REAGENTS (CLASSICAL FORMULA)*

Casein Peptone	g
Lactose	g
Sucrose	g
Sodium Chloride5.0	g
Yeast Extract	g
Phenol Red0.08	g

pH 6.8 ± 0.3 @ 25°C (Post terminal sterilization)

*Adjusted as required to meet performance standards.

PRECAUTIONS

This product is For Laboratory Use only. It is not intended use for in the diagnosis of disease or other conditions.

PREPARATION OF DEHYDRATED CULTURE MEDIUM

- 1. Suspend 50.6 g of medium in 1000 mL of demineralized water.
- 2. Heat to boiling with agitation to completely dissolve.
- 3. Sterilize by autoclaving at 121°C for 15 minutes or following established laboratory procedures.
- 4. Cool media to 50°C and add solution of the sterile filtered antibiotics¹, mix and pour into plates.

PROCEDURE

- 1. Prepare a sample using 1:10 dilution of NLT one (1) gram of product to be examined.
- 2. Use 10mL or the quantity corresponding to 1g to 1mL to inoculate a suitable amount of soybean-casein digest broth as determined during method suitability.
- 3. Mix thoroughly.
- 4. Incubate at 30-35°C for 48 72 hrs.
- 5. Subculture by streaking on a plate of BCSA for USP<60>.
- 6. Incubate plate aerobically at 30-35°C for 48 72 hrs.

Gentamicin	10.0 mg
Vancomycin	2.5 mg
Crystal Violet	2.0 mg
Polymyxin B	600,000 Ŭ
Agar	
Demineralized Water	1000 0 ml

QUALITY CONTROL

Each lot of the Burkholderia Cepacia Selective Agar for USP<60> has been manufactured, packaged, and processed in accordance with current Good Manufacturing Practice regulations. Testing of control organisms should be performed in accordance with established laboratory quality control procedures.

CONTROL

Burkholderia cepacia ATCC[®] 25416 Burkholderia cenocepacia ATCC[®] BAA-245 Burkholderia multivorans ATCC[®] BAA-247 Pseudomonas aeruginosa ATCC[®] 9027 Staphylococcus aureus ATCC[®] 6538 INCUBATION

Aerobic, up to 72 h @ $30-35^{\circ}$ C RESULTS

Good growth with yellow to pink-yellow zone Good growth with pink to red zone Good growth with pink to red zone Inhibition (partial to complete) Inhibition (partial to complete)

LIMITATION

1. This formulation does not contain a selective agent against yeast or filamentous fungi.

BIBLIOGRAPHY

1. The United States Pharmacopeia. National Formulary. <60> Microbiological Examination of Nonsterile products – Test for Burkholderia cepacia complex. Rockville, MD.

 $\mathsf{ATCC}^{\circledast}$ is a registered trademark of American Type Culture Collection. IFU 110245, Revised April 17, 2020

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