OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

SIGNAL BLOOD CULTURE SYSTEM BC0100M

SIGNAL BLOOD CULTURE SYSTEM **BC0100M**

The OXOID SIGNAL Blood Culture System is used to culture samples of blood collected from patients where the condition of bacteraemia is suspected.

Each kit (20 tests per pack) to contain the following:-

BC102	A sealed blood culture bottle containing 84 ± 2ml of broth medium.
BC101	A growth indicator device which has been given a dose of gamma-irradiation (25-40kGy), and is vented through a 0.2 micron hydrophobic membrane.
	Instruction leaflet.

Formula

Tryptone Soya Broth	grams per litre	10.0
Gelatin peptone		10.0
Yeast extract		5.0
Meat extract		5.0
Sodium chloride		8.0
Potassium nitrate		2.0
Glucose		1.0
L-arginine		1.0
Sodium pyruvate		1.0
Gelatin		1.0
Sodium thioglycollate		0.5
Cysteine HCl		0.4
Sodium bicarbonate		0.4
Phosphate buffer		0.3
Sodium polyanethol sulphonate		0.3
Dithiothreitol		0.2
Adenine sulphate		0.01
Sodium succinate		0.01
Ammonium chloride		0.008
Magnesium sulphate		0.008
Menadione		0.005

Physical Characteristics

Straw-coloured medium
Clarity - passes test
Volume check - passes test
Vacuum check - passes test
Sterility check - passes test
Dead cell count - passes test
pH - 7.0 ± 0.2 at 25°C

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

SIGNAL BLOOD CULTURE SYSTEM BC0100M

Buffering capacity - passes test

Constituents of Blood Culture Media

Constituents of Blood Culture Media are pre-tested with the following quality control organisms and must perform in accordance with Product QC Specification.

Microbiological Tests using Optimum Inoculum Dilution

The total inoculum challenge for each test organism per bottle is 10-50 colony-forming units (cfu).

Clostridium perfringens	ATCC®13124
Bacillus cereus	ATCC®10876
Bacteroides fragilis	ATCC®25285
Clostridium novyi	ATCC®27606
Escherichia coli	ATCC®25922
Fusobacterium nucleatum	ATCC®10953
Haemophilus influenzae	ATCC®19418
Klebsiella pneumoniae	ATCC®29665
Neisseria meningitidis	ATCC®13077
Pseudomonas aeruginosa	ATCC®27853
Staphylococcus aureus	ATCC®25923
Staphylococcus epidermidis	ATCC®14990
Streptococcus pneumoniae	ATCC®6303
Streptococcus mutans	ATCC®25175
Candida albicans	ATCC®10231
Prevotella bivia	ATCC®29303

Performance

Each lot of Signal Blood Culture System is tested using the following quality control organisms and must perform in accordance with Product QC Specification.

Control Organisms

Clostridium perfringens	ATCC®13124
Streptococcus pneumoniae	ATCC®6303
Candida albicans	ATCC®10231

Precautions - refer to product leaflet

All blood samples should be considered infectious and handled with care.

OXOID QUALITY ASSURANCE PRODUCT SPECIFICATION

SIGNAL BLOOD CULTURE SYSTEM BC0100M

Although the majority of blood cultures are negative after incubation, they should be sterilized by autoclaving at 121°C for 15 minutes before being discarded. Do not separate the bottle and the growth indicator device before sterilization.

User Quality Assurance - refer to product leaflet

1. Examine the bottles of broth for turbidity and/or change of colour before adding any blood. Discard the bottles showing abnormal characteristics.

2. If further user quality control is required, it is recommended that 3 aerobes and 1 anaerobe from the above list be used.

Inoculation Procedure - refer to product leaflet

1. Inoculate up to 10ml of blood.

2. Place inoculated bottle at 36 ± 1°C for 1 hour before inserting Signal device.

3. Continuously shake for 24 hours at 36 ± 1°C.

4. Incubate at 36 ± 1°C for at least 7 days or until positive. Terminal subculture is recommended.

5. Examine for positive and negative bottles. Subculture positives.

Revision History

Section / Step	Description of Change	Reason for Change	Reference
Kit contents	Clarity of irradiation dose for BC101	Change control	BT-CC-3063

.