Aerobic Blood / Sterile Body Fluids Culture Bottle (Colorimetric Method)

[Package Specification]:

Pack Size: 50 bottles / box, 100 bottles / box, 200 bottles / box
Product Code: CFA-01, CFP-03, CFL-04

[Intended Use]:

Blood cultures are used for early diagnosis of bacteremia and sepsis. The Aerobic bottle (CFA-01) allows preferential growth of aerobic and facultative anaerobic microorganisms. The Aerobic Pediatric bottle (CFP-03) allows growth of aerobic and facultative anaerobic organisms from pediatric blood specimens wherein the volume drawn may be low. The L-aerobic bottle (CFL-04) allows growth of lytic forms of aerobic and facultative anaerobic microorganisms in patients already on treatment and also supports growth of yeasts and filamentous fungi. All the above bottles can be used for recovering pathogens from sterile body fluids as well. The principle use of these bottles is with Render blood culture instruments (BC32, BC64, BC128 and BC256).

[Principle]:

The specimen to be tested (blood / sterile body fluid) is inoculated into the respective bottle as per requirement. The bottle is then loaded into the Render blood culture instrument for incubation and continuous monitoring. Each bottle consist of nutrient substances (refer contents below) which support the growth of the respective group of micro-organisms. A continuous swing motion enhances the probability of growth. Each bottle has a colorimetric substrate at the bottom that can change color (from aquamarine to yellow) on detecting CO_2 produced by the growth of the micro-organisms in the broth medium. The Render Blood Culture Instrument has an in-built sensor at the base of each vial pocket that scans the vial every ten minutes for an increase in its optical density which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of microorganisms and should be confirmed further using standard microbiological practices.

[Contents]:

Each Culture bottle is a transparent cylindrical vial made of polycarbonate with a carbon dioxide sensor at the bottom. The vials contain liquid culture media and gases and are sealed with a butyl rubber sealing.

Main components of these liquid culture media are as follows:

1. Aerobic Culture Bottle (CFA-01): Each bottle consists of 30mL of broth that contains peptone 10g, yeast 4g, BHI 4g, vitamin B6 0.01g, SPS 0.015g, ion adsorbing resin 4g, X factor 0.005g and dispensed with added CO_2 & O_2.
2. Aerobic Pediatric Culture bottles (CFP-03): Each bottle consists of 20mL of broth that contains peptone 10g, yeast 4g, BHI 4g, vitamin B6 0.01g, SPS 0.015g, ion adsorbing resin 4g, X factor 0.005g and dispensed with added CO_2 & O_2.
3. L-Aerobic Culture bottles (CFL-04): Each bottle consists of 30mL of broth that contains peptone 10g, yeast 4g, BHI 4g, vitamin B6 0.01g, SPS 0.015g, ion adsorbing resin 4g, X factor 0.005g, NaCl 40g and dispensed with added CO_2 & O_2.

[Storage and Stability]

Store the Culture Bottle at 15~30^0 C, away from direct sunlight.
The shelf life of the Culture Bottle is one year from the date of manufacture as mentioned on the label of the culture bottle.

[Specimen Collection & Inoculation of the bottles]:

1. Check the culture bottle before use. The liquid media in the bottle should be transparent except for the resin granules. If the liquid media is turbid or has changed color, the bottle is contaminated and inappropriate for use.
2. Appropriate specimen collection (blood / body fluids) and aseptic skin precautions are critical to reduce contamination.
   a. Clean the skin with alcohol (70% isopropyl or ethyl alcohol).
   b. Follow with tincture of iodine or chlorhexidine.
   c. Swab the site of collection starting at center and moving out concentrically.
   d. Allow sufficient time (1 - 2 minutes) for antiseptic to have effect on skin.
   e. Venipuncture site should not touch again.
3. Remove the flip-cap of the bottle and sterilize the top of the bottle with 75% alcohol to avoid contamination of the patient specimen while inoculating the bottle.
4. Aseptically, add enough specimens (as mentioned on the label) into the culture bottle. Inadequate specimen may lead to erroneous results.

[Processing & Interpretation of the bottles]:

1. Once inoculated with the specimens, the culture bottles should be loaded on to the Render Blood Culture Instrument as soon as possible (refer Render Blood Culture Instrument Manual).
2. Prior to loading the vial onto the instrument, check the color of the sensor at the bottom of the vial. In case, the sensor has already changed color from aquamarine to yellow, the bottle should be presumed positive and not loaded onto the instrument. The presumed positive bottle should then be processed as mentioned below.
3. Once loaded onto the instrument, the instrument monitors the bottle for positivity every 10 minutes and will be flagged as positive once the colorimetric substrate detects the growth of micro-organisms. In case of no growth of micro-organisms, at the end of the 5 day incubation protocol, the bottle will be flagged as negative.
4. All bottles flagged positive, should be removed from the instrument, a secondary smear prepared to confirm the growth of the micro-organisms and taken up for further processing (sub-culture, identification and antibiotic susceptibility) as per the laboratory's protocol. In a miniscule percentage of cases, the smear prepared from the positively flagged bottle may reveal no micro-organisms, and such vials should be placed in the laboratory incubator and visually examined from time to time till the end of incubation protocol for the change in color of the sensor.
5. All bottles flagged negative, should be removed from the instrument and a terminal smear may be prepared to rule out false negativity, in case the laboratory protocol mandates the same.

[Quality control]

Frequency of quality control testing should be according to local guidelines. Quality control certificates are provided with each carton of media. Quality control certificates list test organisms, including ATCC cultures specified in the CLSI standard M22, Quality control for commercially prepared Microbiological culture media.
Organisms listed on the Quality Control Certificate for these medium are as follows:

1. Aerobic culture bottles (CFA-01):
    a. *Streptococcus pneumonia* ATCC 49619
    b. *Candida albicans* ATCC 18804
    c. *Staphylococcus aureus* ATCC 25923
    d. *Escherichia coli* ATCC 25922
    e. *Streptococcus pyogenes* ATCC 19615
    f. *Pseudomonas aeruginosa* ATCC 27853
    g. *Alcaligenes fecalis* ATCC 8250
    h. *Hamophilus influenzae* ATCC 49247
    i. *Neisseria meningitidis* ATCC13090

2. Aerobic Pediatric Culture bottles (CFP-03):
    a. Streptococcus pneumonia ATCC 49619
    b. Candida albicans ATCC 18804
    c. Staphylococcus aureus ATCC 25923
    d. Escherichia coli ATCC 25922
    e. Streptococcus pyogenes ATCC 19615
    f. Pseudomonas aeruginosa ATCC 27853
    g. Alcaligenes fecalis ATCC 8250
    h. Hamophilus influenzae ATCC 49247
    i. *Neisseria meningitidis* ATCC13090

3. L-Aerobic Culture bottles
    a. Candida albicans ATCC 18804
    b. Staphylococcus aureus ATCC 25923
    c. Escherichia coli ATCC 25922
    d. Streptococcus pyrogenes ATCC 19615
    e. Pseudomonas aeruginosa ATCC 27853
    f. Alcaligenes fecalis ATCC 8250

[Performance characteristics]

Render blood culture automated system is designed to give comparable performance to CLSI Quality control for commercially prepared Microbiological culture media M22.

[Precautions]

1. Please note the expiration date and use the bottles within the valid period.
2. Please read the pack insert carefully before use and stop using if any turbidity ,sediment or color change is found in the culture media
3. Please collect specimens properly, inoculation of culture media in time and proper operation are critical for improving positive detection and accuracy.
4. The product is single-use and for IVD only, please do not use if the package is broken or words on the package is illegible.
5. Once inoculated with the patient specimen, the bottle is a biohazard, and necessary protective measures for laboratory personnel should be followed. All waste should be disposed of as per local biomedical waste guidelines.

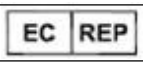
[Limitations]:

1. The results of the test depend on appropriate aseptic specimen collection, load of the bacteria in the blood stream at the time of collection and the amount of blood inoculated into the bottle. Increasing the number of blood culture sets may increase the positive detection rate.
2. The Render blood culture bottles support the growth of most of the clinically significant bacteria and yeasts, when present in significant numbers in the patients' blood. Under some circumstances, some fastidious bacteria do not grow in the Render Aerobic culture media and such fastidious bacteria may need special culture media and culture conditions.
3. For bacteria that can be seen on smear of a positive bottle, but do not grow in regular sub-culture media, need to be sub-cultured in appropriate enriched media that supports the growth of that bacterium.
4. Under some circumstances, some bacteria can grow in culture media but cannot generate enough carbon dioxide to allow the sensor to detect the positivity, may cause false negative results. A terminal smear on all negative bottles may help detect such cases.
5. Excess inoculation of blood (over 10ml), a high WBC count, may lead to false positive flagging.
6. For organisms that are micro-Europhilic or are facultative anaerobes, a simultaneous culture in aerobic & anaerobic bottle is advisable.

[Bibliography]

1. Patrick R.Murray, Mannal of clinical Microbiology, 7th edition
2. Glatt, A.E.,W.Mc Cormack. And D.Taylor-Robison 1989. Genital mycoplasma, P279-293 in sexually Transmitted Disease, 2nd, McGraw-Hill Book co. New York,N.Y.
3. Yumei Wen, "Microbiology of Modern Medicine",1st edition, Shanghai Medical University Press
4. Yingwu Ye, Shusan Wang etc. "National Standard Clinical Practice",2nd edition, Beijing People's republic of china Department of Medical Administration

[Explanation of symbols]

Symbols	Explanation
	Manufacturer
	Use –by date
	Batch code
	Temperature limit
	Consult instructions for use
	Caution
	***In vitro*** diagnostic medical device.
	Sterilized using steam or dry heat
	Authorized representative in the European Community

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