Instruction for Use

AmpuSafe® 102-18

Transport Media System

Cat# of Finished Product	Medium Contained
EM09-01-22	Amies
EM09-01-26	Amies+0.2%Agar
EM09-01-25	Cary-Blair
EM09-01-27	Cary-Blair+0.2%Agar

INTENDED USE

AmpuSafe®102-18 is a member of the family of ready-to-use devices intended for the collection, transport and preservation of specimens for bacteriological examination.

SUMMARY

In microbiological testing, one of the routine but important steps is the collection and safe transportation of a specimen from the sampling site to laboratory. This can be accomplished by using the **AmpuSafe®102-18** collection and transport devices. Enclosed in a sterile **AmpuSafe®102-18** device are a built-in swab and a prefilled liquid or semi-solid media storage. Operators only need to follow a very simple procedure to complete sample collection/treatment before transport for further microbiological testing.

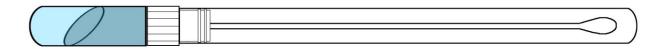
The transport media (Amies, Cary-Blair, with or without agar) used in **AmpuSafe®102-18** system are non-nutritious to prevent microbial proliferation. The composition of the media is chemically defined so that organisms in the sample material are protected from drying and other undesired environmental factors; the viability of the organism being maintained during the transit to the laboratory.

Compared to traditional transport media devices, the new and unique design of the AmpuSafe®102-18 offers following advantages:

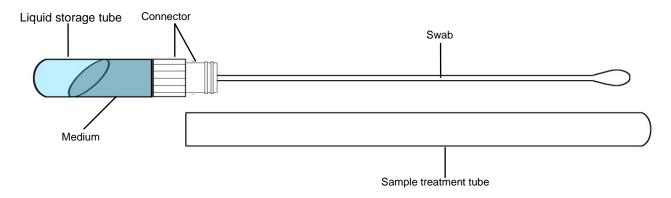
- 1. Better product stability:
 - The use of sealed solution storage helps prevent the penetration of atmospheric air into and evaporation of the media, which are two common causes that affect the product stability.
- 2. Reduced chance of contamination:
 - As the swab is an integral part of the all-in-one system the device transportation and sample collection/treatment becomes less cumbersome resulting in reduced chance of contamination from/to environment and operators, and cross contamination between samples.

The device is composed of a liquid storage tube, a connector, a swab and a sample treatment tube (Refer to Illustrations 1 and 2).

Illus 1: AmpuSafe®102-18 device



Illus 2: Structure of the AmpuSafe®102-18 device



MATERIAL PROVIDED

1. AmpuSafe®102-18 device

STORAGE AND STABILITY

- 1. Store the **AmpuSafe**®102-18 device at room temperature (2-25°C)
- 2. Refer to the label on the device for shelf life. Do not use beyond expiration date.

OPERATION PROCEDURE (Refer to Illus. 3)

Before using the device, restore the temperature of the device to room temperature.

- 1. Hold the connector with one hand and remove the sample treatment tube with another hand to pull out the swab.
- 2. Collect specimen with the swab and quickly insert the swab back into the sample treatment tube. Push the sample treatment tube against the connector to ensure that the tube is clamped securely to the connector and closed well.
- 3. Place the device vertically so that the liquid storage tube is on top. Hold the connector with one hand and twist the liquid storage tube counterclockwise with another hand until resistance is felt. The liquid storage outlet is opened.
- 4. Squeeze the liquid storage tube to expel through the connector the liquid or semi-solid medium into the bottom of the sample treatment tube to soak the swab tip. (There should be enough pre-filled medium to completely wet the swab tip.)
- 5. Hold the connector with one hand and twist the liquid storage tube all the way back clockwise with another hand to close the outlet of the liquid storage tube until the gap between the liquid storage tube and the connector is completely closed.

6. Send the device with specimen for further testing as soon as possible.

WARNING AND PRECAUTION

- This device is for in vitro use only.
- 2. Read Instruction for Use carefully before using the device.
- 3. Use this device before expiration date.
- 4. Discard the device if there is any leakage or swab is exposed outside of the device before use.
- 5. Once the device is open, use it immediately.
- 6. Replace the swab in the sample treatment tube immediately after sample collection and proceed with the OPERATION PROCEDURE.
- 7. Consider all specimens as potentially infectious and take universal precautions when handling specimens. Specimens must be shipped in accordance with applicable national and international regulations.
- 8. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
- 9. This device is a disposable item for one time use. Do not reuse it to avoid cross-contamination.

Illus. 3 Operation Procedure (Refer to the section of **OPERATION PROCEDURE** for detailed instruction)

