

Instruction for Use

AmpuSafe® 102B-19

Sample collection and treatment System

Cat# of Finished Product	Buffer Contained
EM09-01-23	Sample diluent

INTENDED USE

AmpuSafe®102B-19 is a member of the family of ready-to-use systems intended for the collection, transport and treatment of specimens.

SUMMARY

Specimen collection, treatment and transport are always critical aspects of any given testing regardless of its discipline and field of application as they can directly affect the quality of a specimen and in turn the performance of a test.

The **AmpuSafe®102B-19** device was designed to help ensure the quality of specimens by providing an easy-to-operate all-in-one self-contained system with a built-in swab, a pre-filled sample diluent and a built-in liquid outlet nozzle (the dropper). Operators only need to follow a very simple procedure to safely complete specimen collection, treatment, transport and application for testing.

Compared to traditional specimen treatment methods the new and unique design of the **AmpuSafe102B-19** offers following advantages:

1. Product stability:

The use of sealed solution storage helps reduce the penetration of atmospheric air into and evaporation of solution.

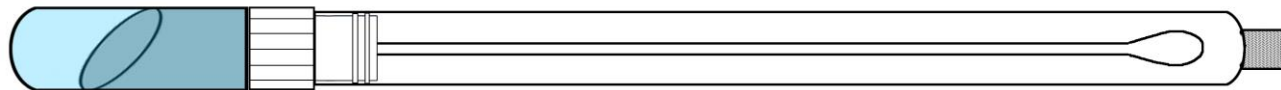
2. Reduced chance of contamination:

The built-in swab and the pre-filled sample diluent make specimen collection/treatment/transport less cumbersome. The built-in dropper serves to facilitate safe application of treated specimen to testing devices. All these result in reduced chance of contamination from/to environment and operators, and cross contamination between samples.

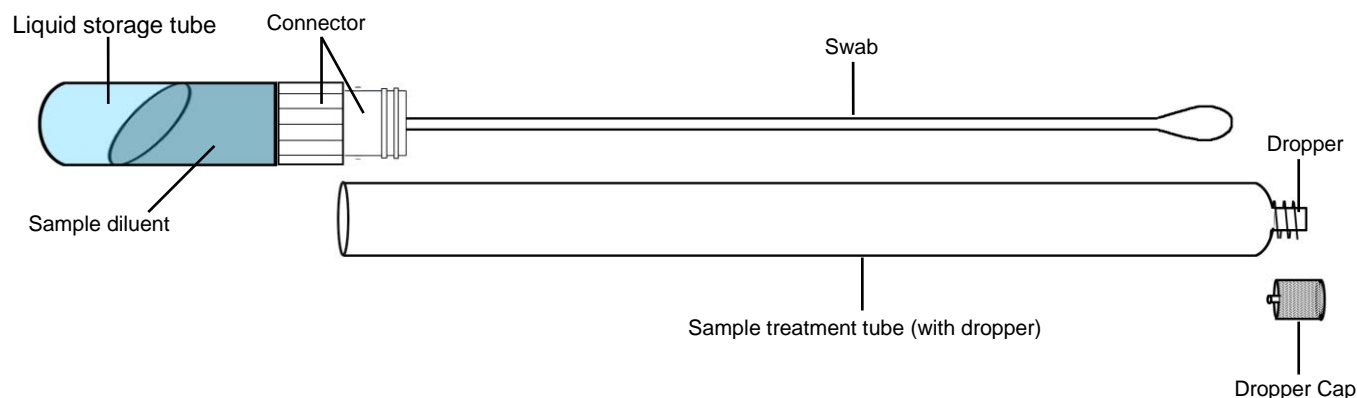
DEVICE COMPOSITION AND CONFIGURATION

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

Illus 1: **AmpuSafe®102B-19** device



Illus 2: Structure of the **AmpuSafe®102B-19** device



MATERIAL PROVIDED

1. **AmpuSafe®102B-19** device

STORAGE AND STABILITY

1. Store the **AmpuSafe®102B-19** 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. Hold 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 into the bottom of the sample treatment tube to soak the swab tip. (There should be enough pre-filled liquid to completely wet the swab tip.)
5. Squeeze the head of the sampling swab across the wall of the sample treatment tube, so that the sample is fully released into the diluent. The sample is ready for transport.
6. If the liquid needs to be dispensed, hold the device horizontally and unscrew the dropper cap of the sample treatment tube.
7. Hold the device vertically and squeeze the tube wall of the sample treatment tube to make the liquid drip out through the dropper for further testing.
8. At the end of the test, rotate the dropper cap back onto the device to prevent the sample from contaminating the environment.

WARNING AND PRECAUTION

1. 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.

PRODUCT REGISTRATION No.:

Machinery & Equipment 20171175, issued by Shanghai Hongkou Division

MANUFACTURER:

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

