

# Saliva Collection Kit

REF BSC91



## Instructions for use

### INTENDED USE

Saliva Collection Kit is intended for collection, transport and preservation of human clinical saliva or sputum specimens to be analyzed by nucleic acid-based assays.

For *in vitro* diagnostic use only. For professional use only.

### PRINCIPLES

Saliva Collection Kit collects saliva or sputum samples through the sampling funnel, and saves the samples in the media in sample collection tube. The media in sample collection tube contains ingredients that effectively inhibit DNase/RNase activity and can stably preserve viral nucleic acid in various samples for a long time -20°C without degradation. This product is simple and convenient to use, can be widely used in hospitals, research institutes and others to collect and transport saliva samples at room temperature.

### PRODUCT DESCRIPTION

Cat#	Kit components	Media in sample collection tube	Main compositions
BSC91X1-B	Collection funnel Sample collection tube Collection tube cap	2 mL	Surfactant, salt solution

### WARNINGS AND PRECAUTIONS

- **All specimens should be considered potentially infectious. It's recommended that the reagents and specimens be handled in accordance with local standards, regulations and other appropriate biosafety practices.**
- For *in vitro* diagnostic use only (IVD).
- The kit is intended for professional use.
- Check the expiration date prior to use. Do not use expired kits.
- Check the media carefully before use. The media is a light pink transparent liquid, do not use if there is any visible discoloration, impurity, spot or blot.
- DO NOT use if a) there is evidence of damage or contamination to the product, b) there is evidence of leakage, c) the color of the media has changed, or d) there are other signs of deterioration
- Read the instructions for use carefully before performing the sample process.
- **Don't drink or touch the media in sample collection tube. If the media is accidentally splashed on the skin, wipe it with clean paper or cloth immediately, and rinse with plenty of water. See a doctor for further treatment if necessary.**

- Do not shake the kit to avoid foam. Leave the kit to stand for 5mins if there is plenty of foam.
- Each kit is for single use only. Do not reuse the kit.
- Once the tube is opened, use the product as soon as possible.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are collected and / or handled.
- Do not rinse or irrigate the collection funnel before the collecting process.
- If the media in the sample collection tube are spilled at any time during the collection procedure, use a new kit. Failure to use a new kit may invalidate the test results.
- Use personal protective equipment such as (but not limited to) gloves, eye protection, and protective coats when collecting the specimens.
- Avoid mixing the reagent with strong acids or bases.
- Only one tube should be open at any given moment during pipetting steps. All other tubes and vials should be kept closed and physically separated from the one being handled.
- Avoid multiple repeated freeze-thaw cycles.
- Dispose of used/ unused kit reagents and specimens according to local, state, and federal regulations.

## **STORAGE AND STABILITY**

The kit must be stored in its original packaging at  $\leq 30^{\circ}\text{C}$  away from light for up to 12 months.

Do not overheat or freeze prior to use.

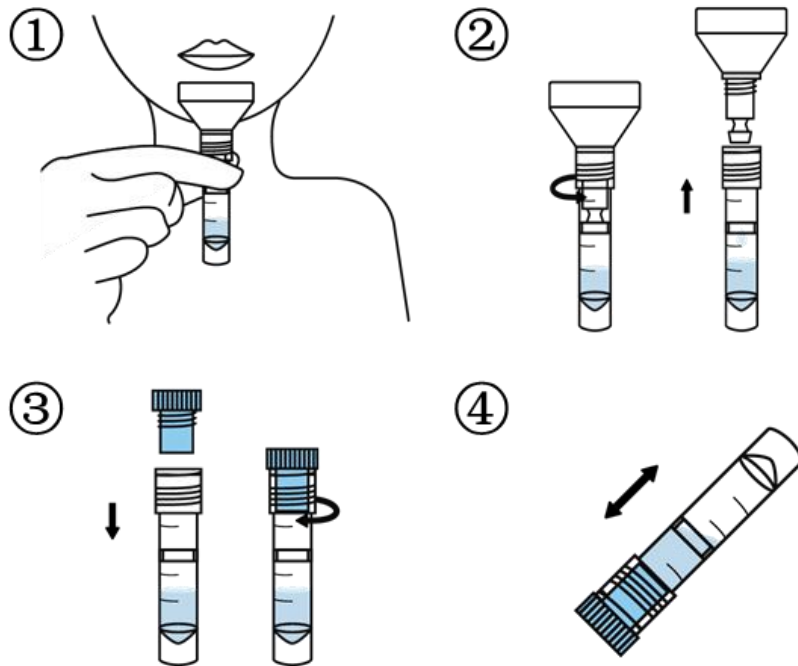
Do not open the kit until you are ready to perform testing.

## **PROCEDURE**

### ***Specimen collection***

***Note: Use personal protective equipment such as (but not limited to) gloves, eye protection.***

1. Applicable sample types: saliva, sputum
2. Open the kit, remove the items from packaging.
3. Label the sample collection tube with identification information.
4. Gently spit saliva/sputum into the collection funnel until the specimens reach the filling line. (Avoid bubbles, see ① in the figure below)
5. Unscrew the funnel from the collection tube in a counterclockwise direction, allow the specimens to flow into the collection tube; (See ② in the figure below)
6. Remove and discard the funnel, and screw collection tube cap onto the tube; (See ③ in the figure below)
7. Invert tube 5 times gently, then the specimen is stabilized and ready for transport or storage. (See ④ in the figure below)



### ***Specimen stability***

It is recommended that specimens be processed as soon as possible after collection.

### **LIMITATIONS**

1. The use of media from any other source could affect the performance of the product.
2. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results.
3. Proper specimen collection is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false or inconclusive test results.
4. Erroneous results may be caused by an incompliance with the storing requirements.
5. Erroneous results may occur when the transport device is not compatible with molecular testing.
6. The device has only been validated to preserve microorganisms used in the analytical studies
7. Nucleic acid will degrade with frozen /thaw cycle.













### **PERFORMANCE CHARACTERISTICS**

Saliva or sputum specimens stored in sample collection tube are allowed to be transported and / or stored at ambient temperatures (less than or equal to 30°C) for up to 30 days or at -70°C or below for up to 6 months.

## REFERENCES

1. Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Available online at: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>
2. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva, Switzerland: World Health Organization; 2004

## SYMBOL

	Manufacturer		In vitro diagnostic device
	CE mark		Authorized Representative In the European Community
	Do not reuse		Consult Instructions for Use
	Catalogue number		Use by date
	Temperature limitation		Batch code (Lot)
	Do not use if package is damaged		Caution

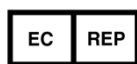
### HANGZHOU BIOER TECHNOLOGY CO., LTD.

1192 BinAn Rd., Binjiang District, 310053 Hangzhou, PEOPLE'S  
REPUBLIC OF CHINA



Website: [www.bioer.com.cn](http://www.bioer.com.cn)

TEL: +86-571-87774575 FAX: +86-571-87774565



### MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

## TECHNICAL SUPPORT

Please dial phone number +86-571-87774567-5211 or 87774575, by fax to +86-571-87774553, or by email to [reagent@bioer.com.cn](mailto:reagent@bioer.com.cn).