

## Manufacturer information

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M012-1EN

# biocomma<sup>®</sup> Transport and Preservation Medium

Instructions for use

## Product Name

biocomma<sup>®</sup> Transport and Preservation Medium (Direct PCR analysis)

## Intended Use

It is used to quickly release the nucleic acid of samples such as nasopharyngeal swabs, oral swabs and saliva. After the nucleic acid is released, it can be directly used as a nucleic acid amplification template for PCR, qPCR, RT-qPCR and isothermal amplification without nucleic acid purification.

## Principles of the Procedure after Specimen Collection

The surfactant component contained in the preservation medium in the sampling tube can quickly inactivate the virus, and after releasing the nucleic acid in the sample, the nucleic acid protection component contained can effectively preserve the nucleic acid.

## Specification & Configuration

Type	Cat. #	Product Description (per pcs)	Package
YMJ	YMJ-TE11	1* virus sampling tube (5 mL), containing 1 mL preservation medium(direct PCR analysis), 1*nasal swab	50pcs/box
YMJ	YMJ-TE12	1* virus sampling tube (5 mL), containing 1 mL preservation medium(direct PCR analysis), 1*oral swab	50pcs/box

## Product Storage/Expiration Date

For optimal performance, the product must be stored in its original package at 5-25°C until the time of use. Do not expose to excessive heat or direct sunlight prior to use.

Product validity period: 12 months.

## Sample requirements

1. This product is suitable for the direct release of nucleic acids in nasopharyngeal swabs, oral swabs, saliva and other samples.
2. The samples need to be stored in time after collection to avoid sample degradation or contamination.
3. If you use this product to process other samples, please contact our technical service department for relevant information.

## Instructions for Use

### 1. Dry swab:

1.1 Take a swab, wipe the sample and put it into the sampling tube, break the swab rod, mix well on the vortex oscillator after closing the lid, and leave it at room temperature for 10 minutes. If it is not tested immediately, the sample should be stored at 5-25°C, but not more than 5 days. For long-term storage, store at -70°C and below. For best performance, complete testing within 24 hours.

1.2 Suck the processed sample as the amplification template, and the amount taken shall not exceed 50% of the PCR reaction system. For example, for a 50 µL detection system, the sample shall not exceed 25 µL.

### 2. Saliva:

2.1 Take 100 µL of saliva to be tested and add it to the sampling tube. After closing the lid, shake and mix well for 10 minutes. If it is not tested immediately, please store the sample at 5-25°C, but not more than 5 days. For long-term storage, store at -70°C and below. For best performance, complete testing within 24 hours.

2.2 Suck the processed sample as the amplification template, and the amount taken shall not exceed 50% of the PCR reaction system. For example, for a 50 µL detection system, the sample shall not exceed 25 µL.

### 3. Samples stored in physiological saline or non-inactivated virus sampling tubes (the samples need to be inactivated):

3.1 The sampling tube containing the sample is placed on the vortex oscillator and mixed thoroughly, and it is allowed to stand for 30 seconds.

3.2 Slightly tilt the sampling tube to suck 200 µL of the mixed sample liquid, transfer to a numbered 1.5 mL centrifuge tube and tightly cap it, and put it in a constant temperature 56°C metal bath for 30 min to inactivate. Centrifuge at 12000rpm for 10min;












3.3 After the centrifugation is completed, open the centrifuge tube, suck the supernatant with a pipette tip, retain the precipitate, add 50 µL of nucleic acid-free extraction preservation solution to each tube, shake well after mixing and let stand for 10 minutes;

3.4 Suck the processed sample as the amplification template, and the amount taken shall not exceed 50% of the PCR reaction system. For example, for a 50 µL detection system, the sample shall not exceed 25 µL.

## Warning & Precautions

1. Please read this instruction carefully before use.
2. biocomma® Transport and Preservation Medium should be used by trained and qualified personnel.
3. Do not use beyond expiration date. Do not use if the original seal of the medium and swab is damaged. Check the outer packaging of the product before use to make sure it is complete with no content overflow. The labeling is unbroken with clear content and no shedding. The preservation solution should be pre-loaded in the sampling tube. It is normal phenomenon to have precipitate at low temperature. biocomma® Transport and Preservation Medium (direct PCR analysis) is a clear solution, do not use if the color of the medium turned turbid, or cloudy.
4. Avoid the medium in contact with eyes and skins.
5. Do not contaminate the tip of the swab before taking samples.
6. Be careful when the swab is inserted into the mouth for oral sampling. Avoid the risk of choking.
7. For single use only. Different patients are prohibited from using the same swab or tube.
8. Specimens for the search of viruses, mycoplasma, chlamydiae and ureaplasmas involves risk of infection, and must be collected and handed using proper PPE against biological risk according to published guidelines and local regulations.
9. Sample sites, condition, volume and timing of specimen collected are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.
10. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.

## Index of Symbols

 Consult instructions for use	 Use-by date	 Temperature limit	 Do not use if package is damaged
 Batch code	 Do not re-use	 Manufacturer	 Handle with care
 Authorized representative in the European Community	 Sterilized using ethylene oxide	 For in vitro diagnostic use only	