

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 irradiation



For in vitro diagnostic use only

Manufacturer information

Manufacturer: Biocomma Limited

Manufacture address: B1605-B1606, Life Science Park, Shenchengtou Creative Factory, Julongshan Rd, Xiuxin Community, Kengzi St, Pingshan Dist, ShenZhen, 518118, P.R.China

Customer service address: Ground FL, Bdg 12, Zhonghaixin Innovative Industrial Park, Ganli Six Rd, Jihua St, Longgang Dist, Shenzhen, 518114, P.R.China

Tel: 86(755)-25431879

Web: www.biocomma.com

E-mail: info@biocomma.com

Manufacture record-filing number: 20200010

Medical device record-filing number/Product technical requirement number: 20200077

Specification approval date and revision date

Approval date: March 31, 2020

Revision date: May 25, 2020

M001-4.1EN

biocomma® Transport and Preservation Medium

Instructions for use

Product Name

biocomma® Transport and Preservation Medium

Intended Use

The biocomma® Transport and Preservation Medium is intended for the collection, storage and transport of viruses, mycoplasma, chlamydiae or ureaplasma specimens from the collection site to the testing laboratory.

Specification & Configuration

| Type | Cat. # | Package |
|------|--|------------|
| YVJ | YVJ-E, YVJ-TE, YVJ-TE1, YVJ-TE2, YVJ-TE3, YVJ-TE4, YVJ-TE5, YVJ-TE6, YVJ-TE7, YVJ-TE8, YVJ-TE9 | 50 pcs/box |
| YMJ | YMJ-E, YMJ-TE, YMJ-TE1, YMJ-TE2, YMJ-TE3, YMJ-TE4, YMJ-TE5, YMJ-TE6, YMJ-TE7, YMJ-TE8, YMJ-TE9 | 50 pcs/box |

Required Materials But Not Provided

Materials required for isolation, extraction and culture of viruses, mycoplasma, chlamydiae and ureaplasma.

Product Description

biocomma[®] Inactivated Transport and Preservation Medium is based on Hank's balanced salt solution enriched with inactivator and nucleic acid protective agents. It is used for nucleic acid extraction of samples such as viruses, mycoplasma, chlamydia and ureaplasma.

biocomma[®] Classic Transport and Preservation Medium is an upgrade from the Hank's solution. Additional various components, such as BSA, HEPES, amino acids, cryoprotectant, etc., are added to enhance the virus integrity. It can be used for nucleic acid extraction of virus, mycoplasma, chlamydia and ureaplasma samples and later virus isolation.

Limitations

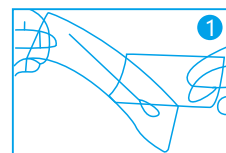
biocomma[®] Transport and Preservation Medium is intended to be used with the medium tubes and swabs provided in the kit. The use of tubes of medium or swabs from any other source could affect the performance of the product.

Warnings & Precautions

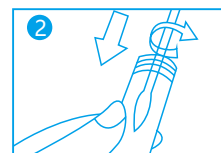
1. Please read this instruction carefully before use.
2. biocomma[®] Transport and Preservation Medium should be used by trained and qualified personnel.
3. Do not use beyond expiration date. Do not use if the original seal of the medium and swab is damaged. Check the outer packaging of the product before 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[®] Inactivated Transport and Preservation Medium is a clear solution, do not use if the color of the medium turned turbid, or cloudy; biocomma[®] classic Transport and Preservation Medium is an orange-red color solution, do not use if the color of the medium has changed from light orange-red.
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.

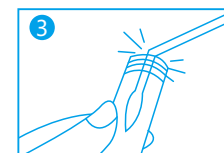
Instructions for Use



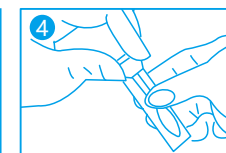
Unwrap the package, take out the swab.



Use the swab to collect samples and put it back into the tube.



Break the swab rod and leave the sampling parts inside the tube.



Screw the lid tightly, and mark on the tube.

Principles of the Procedure after Specimen Collection

When collect specimens with biocomma[®] Inactivated Transport and Preservation Medium, tube can be transported to the laboratory at room temperature (5-25°C) within 7 days. It's better with ice bag. Avoid repeated freeze-thaw cycles. For best performance, complete testing within 24 hours in controlled temperature environment.

When collect specimens with biocomma[®] Classic Transport and Preservation Medium, tube can be transported to the laboratory at 2-8°C within 2 days. If it cannot be delivered to the laboratory within 48 hours, it should be stored at -70°C or below, and ensure that the collected specimens are delivered to the laboratory within 1 week. Avoid repeated freeze-thaw cycles. For best performance, complete testing within 24 hours.

Production Date / Expiration Date

The manufacture production date can be found on the package.
Product validity period: 12 months.

Product Storage

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.

Waste Disposal

Waste must be disposed of in compliance with local legislation. If necessary, take appropriate precautions for infected material.