bioBoaVista	TECHNICAL DATA SHEET	Revision 6.0

VIRAL TRANSPORT MEDIUM (VTM)
FDA K232454
ANVISA #80429030007

Presentation
Vial with 3ml.

Sterilization method
The VTM is provided to the end user as a sterile media per the Centers for Disease Control and Prevention's Standard Operating Procedure: "Preparation of Viral Transport Medium."

Application
The VTM is intended for the collection and transport of upper respiratory clinical specimens containing Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from the collection site to the testing laboratory. The VTM is a culture-based media that is intended to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

Principle
The VTM consists of Hank's Balanced Salt Solution (HBSS) enriched with proteins and sugars with a neutral pH and pH indicator. The VTM contains antibiotics to inhibit the overgrowth of bacteria, yeast, and fungi, maintain cellular integrity, and encourage the preservation of viruses when properly stored.

How to use
1. Open the package of the indicated swab and extract it.
2. Label the sample.
3. Collect the sample. During sampling, the swab end (tip) shall only meet the suspected infection, to reduce contamination risks.
4. After patient sampling, immediately place the tip of the swab into the tube containing the VTM.
5. Break the swab off into vials by aligning the red-marked breakpoint with the upper edge of the vial and bend until the swab breaks off at the mark, leaving the swab tip in the transport tube. Discard the stick and recap the transport tube containing the swab sample.
6. Standard operating protocols for clinical specimen handling and preservation should be followed after the collection. The transport tube containing the swab with nucleic acids from the specimen can be stored for up to 48 hours at 2-8°C or at 25°C.
7. The specimen can then be tested via the culture media method for the presence of a target pathogen.
8. Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines.
9. Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with the internal guidelines of the institution.

Quality Control

Test	Result
Appearance	Liquid medium, reddish orange to pinkish red, clear, might contain slight precipitate
pH at 25°C	7.4 ± 0.2

Results interpretation
The presence of target virus must be tested in accordance with official compendia or internal laboratory methodology.

Precautions and special care
1. For in vitro diagnostic use only.
2. Not intended for therapeutic use.
3. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
4. Do not re-pack.
5. Not suitable for any other application than intended use.
6. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
7. Do not use if the swab is visibly damaged, (i.e., if the swab tip or swab shaft is broken).
8. Do not use calcium alginate swabs or swabs with wooden shafts for collection.
9. Do not use excessive force, pressure, or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft. The swab shaft features a molded breakpoint point designed for the intentional breakage of the swab into a transport tube.
10. Instructions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
11. To be handled by trained personnel only.
12. It must be assumed that all specimens contain infectious microorganisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

Product intended for *in vitro* diagnostic use only.
Restricted for use by professionals. Do not inhale or ingest.
Do not use the product beyond the expiration date, with signs of contamination, or if it has changed color. In the presence of contamination, the product should be immediately discarded.
Do not use the product if the packaging is damaged or tampered with.

Storage
Store the product in a cool, dry place. The storage temperature for the vial with reagent is 2°C to 35°C. Do not overheat or freeze prior to use.

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APPROVED FDA APPROVED

Shelf-life
18 months from the date of manufacture.

Disposal of the product
After use, the product must be handled at the generating unit before environmentally appropriate final disposal, in accordance with official regulations.

Quality Guarantee
bioBoaVista guarantees the quality of its products as long as they are used according to their respective instructions and in accordance with national and international references. bioBoaVista does not take responsibility for the use of its products for purposes other than those described and approved by the company. All clinical diagnoses should be analyzed in conjunction with clinical evidence and not solely based on laboratory results.

References
FDA U.S. Food & Drug Administration. 510(k) Substantial Equivalence Determination. Decision Summary. 510(k) Number K232454.

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