Technical Service Consultants Ltd
Microbiology House, Fir Street, Heywood, Lancashire OL10 1NW, UK
T : +44 (0)1706 620600 F : +44 (0)1706 620445
E : sales@tscswabs.co.uk W : www.tscswabs.co.uk

PROVIR (Modified Hanks) Viral Collection & Transport System

INTENDED USE

The PROVIR Viral Transport System is intended for use in the collection and transport of clinical specimens containing respiratory, enteric and genital viruses from the patient to the laboratory to gain information by molecular analysis and/or culture.

SUMMARY

Swab Kits are the preferred choice for collecting and transporting viral specimens to the laboratory, especially when there is a delay between specimen collection and processing.

The PROVIR viral Transport System consists of a sterile peel-open pouch containing a pre-scored polyester swab and a polypropylene screw-cap vial containing 1 ml of PROVIR viral medium. Polyester provides quick absorption whilst being synthetic and inert releases samples easily without any leaching. Ref

The Viral transport medium contains a number of specialised stabilising amino acids/proteins suspended in a buffered liquid base. This mixture is capable of maintaining the viability of virus RNA/DNA whilst preventing specimen spoilage using antimicrobials.

PROCEDURE PRINCIPLES

Once a specimen is collected with the swab, it is placed immediately into the vial containing the transport medium and processed as soon as possible to achieve optimum recovery. In cases where immediate processing (i.e., within 4 hours) is not possible, specimens can be stored at 4–25°C and processed within 72 hours. For optimal results, storing at refrigerated temperature during transportation will further extend /improve recovery times [Ref]. However, the product has been designed to transport specimens at room temperature.

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The formulation includes specialised proteins/Amino acids for virus RNA/DNA preservation, antibiotics and antimycotics to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH.

FORMULATION

HBSS solution, Sucrose, Bovine serum albumin, Buffered solution, Gelatin, Amino acids, Antibiotics. pH 7.3 ± 0.3 @25 °C.

Formulation may be adjusted/ to meet performance criteria

PROVIR VIRAL medium is straw coloured, clear to slightly opalescent appearance. This variation is a physical characteristic caused by its chemical composition and is normal.

REQUIRED MATERIALS BUT NOT PROVIDED

Materials/equipment suitable for the molecular processing, microscopic examination, cultivation, differentiation, and isolation or identification of viruses from clinical specimens are not provided. Please refer to standard laboratory procedures or referenced standards.

QUALITY CONTROL

All raw materials used in the manufacture of PROVIR VIRAL Transport System are tested and qualified before use. Every lot of PROVIR VIRAL Transport System is tested prior to release for sterility, pH, and anti-microbial activity levels. Representative samples of each lot are further evaluated for their ability to maintain Viral RNA/DNA over the predefined time periods. All viral test isolates and testing procedures were established using the criteria outlined in the Clinical and Laboratory Standards Institute's M40-A2 document. The M40-A2 document for determining performance characteristics of swab transport systems.[21] To determine the performance characteristics of the PROVIR Viral Transport System, viral viability studies were performed. These studies were conducted at two different temperatures to reflect refrigerated (4-8°C) and room temperature (20-25°C) conditions. The swabs from each transport system were inoculated in

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duplicate with a specified titre of select viruses. These swabs were then placed in their respective transport vial and held for 0 and 72 hours; at the designated time intervals the swabs were removed and processed

DEVICE STORAGE

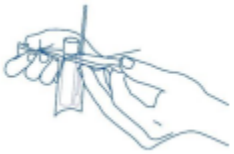
The product must be stored in its original packaging at a temperature between 4 and 25°C until the time of use. Do not overheat or freeze prior to use.

DIRECTIONS FOR USE (Samples should be kept cool until sampling is performed)

STEP 1.

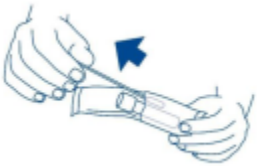
Identity the area to be sampled - The current configuration to ideal for sampling the throat.

STEP 2.



Peel open the pouch using the pull tabs located at one end of the pouch.

STEP 3.



Remove the swab and tube from the peel pouch keeping the transport tube within reach. **Discard the peeled pouch.**

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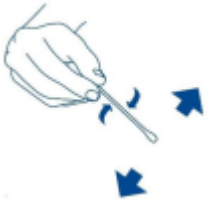
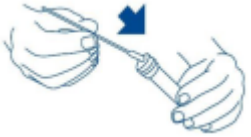
STEP 4.



Swab the area to the sampled.

STEP 5.



When sampling is completed, unscrew the transport tube cap and insert the swab into the tube until the swab tip touches the bottom the tube.

STEP 6.

Pull downwards on the shaft (whilst the swab is held inside the tube) to activate breakpoint. It may be necessary to repeat action using opposite side of shaft if first attempt does not break.

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STEP 7.

Discard redunudant shaft and screw tube cap on tightly.

STEP 8.

Write sample details on label. Store at 4-8°C wherever feasible (or as cool and dry as environment allows) and send to laboratory immediately for analysis.

SPECIMEN COLLECTION, STORAGE & TRANSPORTATION

Proper specimen collection from the patient is critical for successful isolation and identification of infectious targets. For specific guidance regarding specimen collection procedures, consult published reference manuals. To maintain optimum viability, transport the specimens collected using PROVIR Viral System to the laboratory within 4 hours of collection.

Its recommended that specimens are processed as soon as they are received in the laboratory. If immediate delivery or processing is delayed, then specimens should be refrigerated (at 4-8°C) where possible or can be transported at room temperature (20-25°C) and processed within 72 hours. If further processing delay is experienced (over 72 hours), then its recommended that the specimens are frozen at -70°C or colder.

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SPECIMEN PROCESSING

PROVIR VIRAL System specimens should be processed for viral particles using recommended culture media or molecular laboratory techniques which will depend on the specimen type and the sample under investigation. Please use the recommended published guidelines.

PRECAUTIONS & LIMITATIONS

1. **DO NOT REUSE.** Single use Device that is not suitable for re-work or reuse. Only suitable for collection and transport of viruses.

2. In vitro diagnostic use only. Use by trained Professionals where immediate laboratory analysis is possible. Please read and follow the instructions in this package insert carefully and use aseptic techniques.

3. Only use the tubes and swabs provided in the kit. The use of any other externally sourced medium or swab could affect the performance of the device.

4. Do not use beyond expiry stated on vial.

5. The device must be validated and approved when used in combination with other diagnostic kits or instruments prior to their use.

6. DO NOT USE if there is evidence of leakage, the swab is damaged or the pouch is open, or there are signs of sterility failure/contamination.

7. Recovery after 72 hours will be unpredictable and target viruses RNA/DNA may be reduced or lost. Sterile beads may be added where mucous or particularly viscous specimens are taken.

8. Do not use the viral medium for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites. Do not ingest the medium.

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9. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.

10. Do not re-sterilize unused swabs or repack.

11. Use personal protective equipment against biological risk according to published manuals and guidelines.

12. Repeated freezing and thawing of specimens may reduce viability.

13. All clinical specimens should be considered biohazards and handled with care. Use adequate biohazard equipment to protect the operator and the environment during sampling or splashing when removing the captured swab.