∑-VIROCULT®
PRODUCT INSERT

THIS PRODUCT INSERT IS APPLICABLE TO THE PRODUCT CODES DISPLAYED ON THE BELOW TABLE

Product Code	Description	Specimen type/Sampling site
MW950S	Large vial 2.0ml of medium, 1 standard sigma swab	Skin, nose, throat, Rectum, Vagina
MW950S2	Large vial 2.0ml of medium, 2 standard sigma swabs	Skin, nose, throat, Rectum, Vagina
MW950SE2	Large vial 2.0ml of medium, 1 standard, 1 Sigma ENT	Nasopharyngeal, Urogenital
MW950S3	Large vial 2.0ml of medium, 3x standard	Skin, nose, throat, Rectum, Vagina
MW950SENT	Large vial 2.0ml of medium, 1 Sigma ENT	Nasopharyngeal, Urogenital
MW950T	Large Vial 2.0ml of medium only (Tube only*)	
MW951S	Small vial 1.0ml of medium 1 standard sigma swab	Skin, nose, throat, Rectum, Vagina
MW951S2	Small vial 1.0ml of medium 2 standard sigma swab	Skin, nose, throat, Rectum, Vagina
MW951SE2	Small vial 1.0ml of medium 1 standard sigma swab, 1 Sigma ENT	Nasopharyngeal, Urogenital
MW951S2ML	Small vial 2.0ml of medium 1 standard sigma swab	Skin, nose, throat, Rectum, Vagina
MW951SENT	Small vial 1.0ml of medium 1 Sigma ENT	Nasopharyngeal, Urogenital
MW951SENT2ML	Small vial 2.0ml of medium 1 Sigma ENT	Nasopharyngeal, Urogenital
MW951T	Small vial 1.0ml of medium only (Tube only*)	
MW951PF2ML	Small vial 2.0ml of Virocult® medium, 1 PurFlock® swab (white with breakpoint)	Skin, nose, throat, rectum, vagina
MW951HF	Small vial 1.0ml of Virocult® medium, 1 HydraFlock® swab (white with breakpoint)	Skin, nose, throat, rectum, vagina

MW951SPV (Temporary product for Covd-19)	Mini Sigma Virocult, Screw Vial, 1ml, Viscose Swab	Skin, nose, throat, rectum, vagina
MW951SPD (Temporary product for Covid-19)	Mini Sigma Virocult, Screw Vial, 1ml, Polyester Swab	Skin, nose, throat, rectum, vagina

Products with (Tube Only*) in the description are products which are registered as IVD's only.

INTENDED USE

Σ-Virocult® (Sigma Virocult®) Virus Collection and Transport System is intended to preserve the viability and infectivity of viral specimens for viral culture after their collection and during transport from the collection site to the testing laboratory. ∑-Virocult® specimens are processed using standard clinical laboratory procedures for viral and cell culture.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections caused by viruses involves the collection and transportation of a clinical swab specimen from the patient to the laboratory. Specimens containing live viruses may be submitted to a laboratory for diagnosis or confirmation of the patient's illness. Σ-Virocult® tubes contain a liquid medium to keep the specimen moist, and to maintain any viruses in a viable condition until they can be investigated at the laboratory by viral culture. The liquid medium consists of a balanced salt solution for maintaining osmotic pressure within physiological limits and phosphate buffers to stabilize the pH of the medium. For specific recommendations about the collection of specimens for viruses and primary isolation techniques, consult the following ASM publications: Cumitech 15A1, Clinical Microbiology Procedures Handbook2, Manual of Clinical Microbiology3, Clinical Virology Manual4, and Johnson F. B.5

REAGENT FORMULA

Virocult® medium is a balanced salt solution, buffered with disodium hydrogen orthophosphate, and also contains lactalbumin hydrolysate as a stabiliser, and antibiotics to inhibit the growth of any bacterial contaminants in the specimen.

Active ingredients:
Chloramphenicol
Amphotericin

PRECAUTIONS

For Professional use only.
For virology specimens only.
For in vitro Diagnostic use only.
This device is a Single use Device and therefore cannot be reused, it must be assumed that all used devices contain infections organisms and therefore should be handled accordingly, after use all devices must be disposed of according to laboratory regulations for infections waste.
DONOT USE IF PACKAGE SEAL IS BROKEN

IMPORTANT NOTE

When collecting specimen from patient.
Do not use excessive force, pressure or bending while using the swab to collect a specimen from the patient, as this could cause accidental breakage of the swab shaft. Some swab shafts do have a defined breakpoint to allow the swab to be snapped off into the transport tube, but in all cases excessive force must never be used while collecting the specimen.

STORAGE: Sigma Virocult ® should be stored in a dry place at temperatures between + 5°C to 25°C.

DO NOT FREEZE

EXPIRY DATE: Is 12 months from date of manufacture, expiration date is shown on the peel pouch and labelled tube.

MATERIAL SAFETY INFORMATION

The plastic components do not contain latex or PVC.
Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. Prior to discarding, swabs and other contaminated materials must be sterilized by autoclaving. Once a swab sample is collected it should be placed immediately into the transport tube where it comes into contact with transport medium. Swab specimens for virus isolation and/or detection should be submitted to the laboratory as quickly as possible after collection.

SPECIMEN COLLECTION AND HANDLING

Materials provided

Swab for collection of specimen. (MW950T & MW951T are provided without swabs)
Transport tube with Virocult® medium
***There is no swab with MW950T, MW951T**

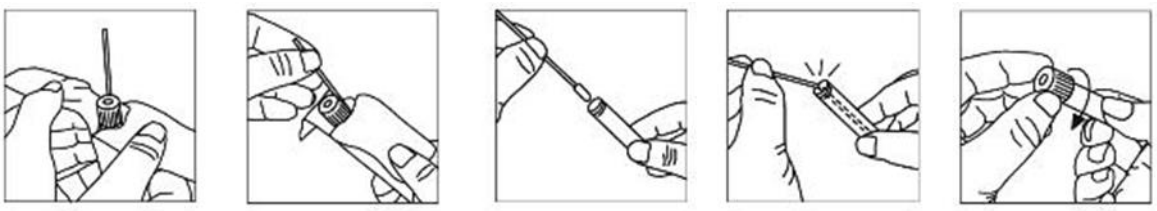
Materials required but not provided

Eagle's Minimum Essential Medium (buffered) or Hanks Balanced Salt Solution (buffered).
Pipette to withdraw 0.2ml fluid from Virocult® tube.
Cell culture facilities and cell lines appropriate for target viruses.

INSTRUCTIONS FOR TAKING SPECIMEN

Before use always check that immediate packaging (peel pouch) is intact, that the tube contains medium and there are no signs of leakage. In case of defect do not use the device. Appropriate protective clothing including sterile gloves should be worn when collecting and handling potentially infectious specimens. Care should be taken to avoid splashes and aerosols when snapping the swab shaft against the tube.

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap by partially unscrewing.
2. Withdraw swab and use to take specimen.
3. Remove cap from vial, insert swab into vial and snap off the non-bud end so that the remaining shaft fits within the vial.
4. Repeat Steps 2 & 3 for second swab if present in pack.
5. Replace cap, and tighten until secure.
6. Transport to laboratory immediately.



PROCESSING METHOD (CULTURE METHOD)

1. Add approximately 2.0ml of Eagle's Minimum Essential Medium or Hanks' solution to the transport tube with the swab in situ.
2. Mix thoroughly using a vortex mixer.

3. Using a pipette withdraw the liquid and add approximately 0.2ml of the suspension to each tissue culture well, dish or tube.
4. In compliance with CLSI M40-A, inoculation of specimens onto cell cultures should be performed within 96 hours of specimen collection.
5. Virus is detected by the appearance of cytopathic effect in the cell culture.

PROCESSING SPECIMENS (MOLECULAR METHOD)

Refer to the test system manufacturer's instructions. Any use with non-culture methods must be validated by the user**.**

QUALITY CONTROL

With reference to CLSI M40-A it is recommended that Herpes Simplex Type 2 ATCC VR-734 be used as a control strain. The swab is inoculated from a suspension containing 5 x 104 TCID per ml and placed into the transport tube. The tube is held at the desired transport temperature (4OC or room temperature) for up to 96 hours. The transport tube is processed as described above ("Processing Specimens") and 0.2ml of suspension is inoculated onto a suitable tissue culture monolayer. Any recovery of virus is acceptable performance.

LIMITATONS

1. This device is NOT SUITABLE FOR THE TRANSPORT OF BACTERIA OR FUNGI because antibiotics are used in the medium.
2. Traces of antiviral reagents at site of specimen prior to sampling may affect recovery of virus
3. Σ-Virocult® has not been validated for use with molecular techniques such as PCR, so any such use must be validated by the user.

REFERENCES

1. Gleaves C. A., R. L. Hodinka, S. L. G. Johnston and E. M. Swierkosz, Cumitech 15A. Laboratory Diagnosis of Viral Infections, p. 7., American Society for Microbiology, Washington D.C., 1994
2. Miller, M. J., and A.L. Warford. Preparation of specimens for inoculation of cell cultures, p. 8.3.1 – 8.3.8. In H.D. Isenberg (ed.), Clinical Microbiology Procedures Handbook. American Society for Microbiology, Washington, D.C., 1992.
3. Chapin, K.C., & F.W. Westenfeld, 2003, Reagents, Stains, Media, and Cell Lines: Virology, p.1250 in Murray P.R., E.J. Baron, J.H. Jorgensen, M.A. Pfaller, & R.H. Yolken, 2003, Manual of Clinical Microbiology, 8th Edition, ASM Press, Washington D.C.
4. Specter, S., R.L. Hodinka, and S.A. Young, 2000, Clinical Virology Manual, 3rd Edition, ASM Press, Washington D.C.
5. Johnson F. B., Transport of Viral Specimens, p. 120 – 131. Clinical Microbiology Reviews, Vol. 3, No. 2, April 1990
6. CLSI. 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A. CLSI (formerly NCCLS) document M40-A [ISBN 1-56238-520-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

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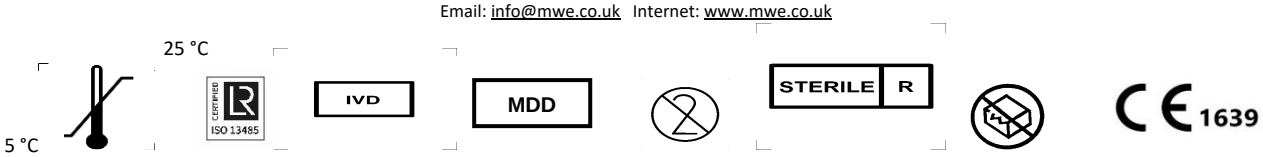

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