

Σ-VCM™ (SIGMA-VCM™)

WITH LIQUID VCM™ FOR VIRUS, CHLAMYDIA & MYCOPLASMA

CODE	DESCRIPTION	SPECIMEN	CODE	DESCRIPTION	SPECIMEN
MW910S	Σ-VCM™ Single standard Sigma Swab, plastic shaft red colour coded cap, 1.0ml medium, With glass beads, Small vial	Mouth, nose, throat, skin, vagina	MW912S	Σ-VCM™ 1 standard Sigma Swab & 1 mini-tip Sigma Swab, plastic shafts, red colour coded cap, 1.0ml medium, With glass beads, Small vial	Nasopharyngeal, paediatric, urogenital, vagina
MW910PF	Σ-VCM™ Single standard PurFlock® Swab, plastic shaft red colour coded cap, 1.0ml medium, With glass beads, Small vial	Mouth, nose, throat, skin, vagina	MW915T	Σ-VCM™ Medium only, red colour coded cap, 1.0ml, With glass beads, Small vial (Tube only*)	
MW910PF2ML	Σ-VCM™ Single standard PurFlock® Swab, plastic shaft red colour coded cap, 2.0ml medium, With glass beads, Small vial	Mouth, nose, throat, skin, vagina	MW916T	Σ-VCM™ Medium only, red colour coded cap, 3.0ml, With glass beads, Small vial (Tube only*)	
MW910HF2ML	Σ-VCM™ Single standard HydraFlock® Swab, plastic shaft red colour coded cap, 2.0ml medium, With glass beads, Small vial	Mouth, nose, throat, skin	MW918S	Σ-VCM™ Single standard Sigma Swab, plastic shaft red colour coded cap, 3.0ml medium, With glass beads, Large vial	Mouth, nose, throat, skin, vagina
MW911S	Σ-VCM™ Single mini-tip Sigma Swab, plastic shaft red colour coded cap, 1.0ml medium, With glass beads, Small vial	Nasopharyngeal, paediatric, urogenital	MW919S	Σ-VCM™ Single mini-tip Sigma Swab, plastic shaft red colour coded cap, 3.0ml medium, With glass beads, Large vial	Nasopharyngeal, paediatric, urogenital
MW911PF	Σ-VCM™ Single mini-tip PurFlock® Swab, plastic shaft red colour coded cap, 1.0ml medium, With glass beads, Small vial	Nasopharyngeal, paediatric, urogenital	MW919PF	Σ-VCM™ Single mini-tip PurFlock® Swab, plastic shaft red colour coded cap, 3.0ml medium, With glass beads, Large vial	Nasopharyngeal, paediatric, urogenital
MW911PF2ML	Σ-VCM™ Single mini-tip PurFlock® Swab, plastic shaft red colour coded cap, 2.0ml medium, With glass beads, Small vial	Nasopharyngeal, paediatric, urogenital	MW920S	Σ-VCM™ 1 standard Sigma Swab & 1 mini-tip Sigma Swab, plastic shafts, red colour coded cap, 3.0ml medium, With glass beads, Large vial	Nasopharyngeal, paediatric, vagina, urogenital,
MW913PF2ML	Σ-VCM™ Single Flexible Shaft Microfine Tip PurFlock®, 2.0ml medium, With glass beads, Small vial	Nasopharyngeal, paediatric, urogenital	MW921S	Σ-VCM™ Two standard Sigma Swabs, plastic shaft red colour coded cap, 3.0ml medium, With glass beads, Large vial	Mouth, nose, throat, skin, vagina



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MW914PF2ML	Σ-VCM™ One standard PurFlock® Swab and one Mini Tip PurFlock® Swab, 2.0ml medium, Small vial	Nasopharyngeal, paediatric, vagina, urogenital	MW924S	Σ-VCM™ Two standard Sigma Swabs, plastic shaft red colour coded cap, 1.5ml medium, Large tube, No glass beads	Mouth, nose, throat, skin, vagina
MW910S3ML	Σ-VCM™ Single standard Sigma Swab, plastic shaft red colour coded cap, 3.0ml medium, With glass beads, Small vial	Mouth, nose, throat, skin, vagina	MW926T	Σ-VCM™ Medium only, red colour coded cap, 3.0ml, With glass beads, Large vial (Tube only*)	

Products with (Tube Only) in the description are products which are registered as IVD's only (EU Directives and Regulations) .

Intended Use

Σ-VCM™ (Sigma-VCM™) Specimen Collection and Transport System is intended to preserve the viability and infectivity of specimens containing virus, chlamydia, mycoplasma, ureaplasma, and *Neisseria gonorrhoeae* after their collection and during transport from the collection site to the testing laboratory. Σ-VCM™ specimens are processed using standard clinical laboratory procedures for viral and cell culture, or for bacterial culture.

Summary and Principles

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

Reagents

VCM™ medium is a balanced salt solution, buffered with disodium hydrogen orthophosphate and HEPES, with sucrose and lactalbumin hydrolysate as stabilisers, and antibiotics to inhibit the growth of bacterial and fungal contaminants in the specimen.

Active ingredients:

Vancomycin
Colistin
Amphotericin

Precautions

For Professional use only.



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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 infectious organisms and therefore should be handled accordingly.

After use all devices must be disposed of according to laboratory regulations for infectious waste.

DO NOT 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.

Swabs with breakpoints are not suitable for collecting specimens via tracheotomy 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.

Storage

Σ-VCM™ should be stored in a dry place at temperatures between + 5°C to 25°C.

DO NOT FREEZE

Expiry Date

12 months from date of manufacture, expiration date is shown on the tube label, peel pouch, and box label.

Specimen Collection and Handling

Materials provided

Swab for collection of specimen. *

Transport tube with VCM™ Medium

*There is no swab with MW915T, MW916T, MW926T

Materials required but not provided:

Cell culture medium (for virus or chlamydia), or isolation medium (for mycoplasma, ureaplasma, or *Neisseria gonorrhoeae*) Pipette to withdraw inoculation medium from vial. Cell culture facilities and cell lines appropriate for target organisms.

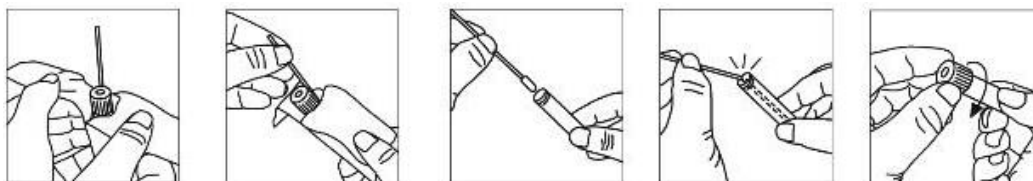
Instructions for Use



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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. The white swab will become attached to the cap, except for large vials and MW911PF, MW911PF2ML, MW913PF2ML and MW911HF2ML.
6. Transport to laboratory immediately.

Processing (Culture)

Virus & Chlamydia

1. Vortex medium to allow glass beads to disrupt cells and release intracellular virus or Chlamydia particles.
2. Medium can be inoculated directly onto suitable cell culture, or diluted prior to inoculation.
3. If medium is to be diluted first use either phosphate buffer, or a suitable balanced salt solution

Mycoplasma or *Neisseria gonorrhoeae*

Medium can be inoculated direct onto suitable agar medium, or transfer an aliquot to a suitable enrichment broth and incubate prior to inoculation.

In compliance with CLSI M40-A, inoculation of specimens onto cell cultures should be performed within 96 hours of specimen collection, or 24 hours for *Neisseria gonorrhoeae*.

(Molecular Method)

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

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 5×10^4 TCID per ml, and placed into the transport tube. The tube is held at the desired transport temperature (4°C or room temperature) for up to 96 hours. The transport



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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.

Limitations

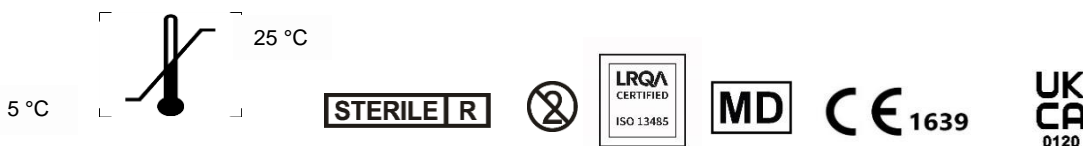
This device is NOT SUITABLE FOR THE TRANSPORT OF BACTERIA OR FUNGI (other than Chlamydia, Mycoplasmas, and Neisseria gonorrhoeae) because antibiotics are used in the medium.

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. Tenover, & R.H. Tenover, 2003, Manual of Clinical Microbiology, 8th Edition, ASM Press, Washington D.C.
4. 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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