

**REF** PMW903-NP, PMW903-OP, PMW903-DS  
**PMW Viral Transport Medium RT Kit**

ISO 9001  
ISO 13485



✓ **Intended Use**

PMW Viral Transport Medium RT Kit is intended for the collection, preservation, and transportation of clinical specimens from the oropharynx, nasopharynx, etc. for diagnosis.

✓ **Summary**

- 1) PMW Viral Transport Medium RT Kit is intended for specimen's preservation and transportation.
- 2) PMW Viral Transport Medium RT Kit prevents dehydration, and was designed to maintain viability of virus existing within the specimen while being transported.

✓ **Composition and Method Principle**

- 1) PMW Viral Transport Medium RT Kit is composed of Viral Transport Medium (VTM) and (dual) flexible regular flocked swabs.
- 2) Viral Transport Medium (VTM) as In Vitro diagnostic medical device (**IVD**)
  - A. Composition  
Bovine Serum Albumin (BSA), Amino acids, Buffered solution, Sucrose, Antimicrobial agents, Phenol red  
Final pH 7.3±0.2 at 25°C  
3mL medium in Ø17×H100 mm skirted tube with screw cap
  - B. BSA and amino acids help to stabilize virus particles and to sustain viability for bacteria, Buffered solution provides essential inorganic ions and maintain pH and osmotic balance. Sucrose acts as cryoprotectant ensuring organs viability during freeze-thaw. Antimicrobial agents are used to prevent microbial growth. Phenol red is the pH indicator ensuring medium integrity at the time of specimen collection.
- 3) (Dual) flexible regular flocked swabs; tool for specimens as **medical device**
  - A. Composition  
Oropharyngeal swab with breakpoint (1 ea) or Nasopharyngeal swab with breakpoint (1 ea)

✓ **Instructions for Use**

- 1) Prior to use, check the packaging for abnormalities or damage.
- 2) Take the intended swab out of the wrapper carefully.
- 3) Collect the specimens using swab.
  - A. **Nasopharyngeal swab:** Tilt the patient's head back slightly about 45° - 70 ° to straighten the passage from the front of the nose, and gently Insert the swab along the base of the nose (not upwards) until it reaches the nasopharynx-gentle rotation of the swab for a few seconds may be helpful.
  - B. **Oropharyngeal swab:** Press the tongue and extract the secretion from the back wall of pharynx.
- 4) Open the cap and place the collected specimen in the medium with applying force to the breakpoint.
- 5) Firmly close the cap.
- 6) Record the patient's name, gender and other information on the external label.
- 7) Transport immediately after collection.

Specimens may be dispatched at room temperature or refrigerated temperature to arrive at the testing laboratory for processing. If a delay in testing or shipping is expected, specimens should be frozen at -70°C or below. Repeated freezing and thawing of specimens should be avoided as may reduce the recovery of viable organisms.

✓ **Appearance (VTM)**

Clear, light orange-red liquid

✓ **Storage**

Store at 2 ~ 25 °C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

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✓ **Shelf Life**

VTM: 1 year from manufacture. Swab: 3 years from manufacture  
 Expiry dates are described in each VTM and Swab.

✓ **Quality Control**

PMW Viral Transport Medium RT Kit complies with Quality Control of Microbiological Transport Systems; Approved Standard (CLSI M40-A) and CDC SOP DSR-052, and all lot number is tested using proper quality control specifications as outlined in the Certificate of Analysis (COA) available for each lot on Xcell Therapeutics website.

✓ **Precautions**

- 1) The product is intended for in-vitro diagnostic use.
- 2) The product must not be used other than preservation of specimens.
- 3) Store at 2 ~ 25°C until the labeled date.
- 4) Do not use beyond expiry date.
- 5) Do not use the product when the container is damaged or the cap is open.
- 6) This product is a single-use device. Do not re-use.
- 7) Specimen may contain pathogenic microorganism and must be handled with care.
- 8) All clinical specimen must be handled with care since they may contain pathogenic microorganisms.
- 9) Use personal protective equipment against biological risks before handling the product.



















✓ **Disposal of Waste**

Must be disposed immediately after use according to national and local regulations in force.

✓ **Packaging**

- 1) 100 VTM tubes with 100 (dual) swabs / pack, 12 packs / box
- 2) 50 VTM tubes with 50 (dual) swabs / pack, 24 packs / box

3) **Table of Symbols**

	Batch code		Catalog number		In Vitro diagnostic medical device
	Use by date		Temperature limitation		Do not reuse
	Manufacturer		Consult accompanying document		Consult instructions for use
	This way up		Handle with care		Fragile
	Keep dry		European Authorized Representative		Keep away from sunlight
	Date of manufacture		CE marking		Don't use if unit package is opened or damaged

This document is available from the online support center:  
<http://xcell.media>

**Manufactured by Xcell Therapeutics Inc.**

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