

# Viral Transport Products

Part	Description	Size
600-102	Viral Transport Medium	3mL
600-107	Saline	3mL
600-108	Phosphate Buffered Saline (PBS)	3mL



Gemini has been supplying viral transport products to states, municipalities, and the [United States Government](#). Learn more about Gemini's efforts during the COVID-19 pandemic [on their website](#).

## Quality:

- Gemini is registered with the FDA as a Class 1 Medical Device manufacturer. Gemini manufactures the VTM under QSR and in compliance with 21 CFR 820.
- Gemini uses gamma irradiated tubes that are DNase and RNase free.
- FBS used in the VTM formulation is gamma irradiated using 25 – 40 KGy.
- The sourcing of the FBS is from a country of negligible risk for BSE/ TSE as determined by the OIE.
- Gemini prepares the intermediates for the VTM (Gentamycin, amphotericin B and HBSS) using USP and/ or ACS grade raw materials when possible.
- Intermediates are also manufactured under QSR and in compliance with 21 CFR 820.
- All tube filling is performed in an ISO 5 environment with environmental monitoring.
- The media is filtered through a 0.2 µm filter prior to filling tubes and a filter integrity test is performed to ensure the filter was operating correctly.
- A Certificate of Analysis is included with each shipment.

## Labeling:

Each tube is labeled with:

- Product name
- Lot number
- Expiration date
- Catalog number
- Caution statements
- Media contents.
- Manufactured by
- Storage condition
- Sterility
- Patient name
- Patient DOB

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## **Viral Transport Medium**

The viral transport media originates from the CDC formulation SOP# DSR-052-03. [1] This product is packaged as 3mL in a 15mL conical tube.

Please note: This is not a kit and does not contain a swab.

**Storage:** 4-8 °C

### **Packaging:**

The product comes in a rack of 25 tubes, which is bagged to ensure the tubes stay within the racks. Each case of VTM holds 30 racks for a total of 750 tubes per 17" x 17" x 17" box. It is packed with three ice pack sheets in the middle of the top layer to keep the product cold during shipment.

## **0.9% Saline**

This product is packaged as 3mL in a 15mL conical tube.

**Storage:** Room Temperature

### **Packaging:**

The product comes in a rack of 25 tubes, which is bagged to ensure the tubes stay within the racks. Each case of Saline holds 33 racks for a total of 825 tubes per 17" x 17" x 17" box. The cases are packed identically to the VTM, except the top layer of tubes has 11 racks instead of 8 since no ice is needed.

## **Phosphate Buffered Saline (PBS)**

This product is packaged as 3mL in a 15mL conical tube.

**Storage:** Room Temperature

### **Packaging:**

The product comes in a rack of 25 tubes, which is bagged to ensure the tubes stay within the racks. Each case of PBS holds 33 racks for a total of 825 tubes per 17" x 17" x 17" box. The cases are packed identically to the VTM, except the top layer of tubes has 11 racks instead of 8 since no ice is needed.

### **Regulatory Compliance**

For the VTM, this would typically require 510(k) approval to use this as part of the viral sample collection but during the COVID-19 pandemic, the FDA has allowed Gemini Bio to distribute the VTM provided that Gemini Bio uses the CDC recipe as the basis for manufacture and the tubes have the following statement, “This product has not been cleared or approved by the FDA” [5]

### **References**

1. Centers for Disease Control and Prevention (CDC) Standard Operating Procedure (SOP) *DSR-052-04: Preparation of Viral Transport Medium*
2. FDA Guidance, *Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff*, July 2020

### **For additional information:**

#### **Brendan Lucey**

Gemini Bio-Products

[blucey@gembio.com](mailto:blucey@gembio.com)

M: 302-287-2385

[gembio.com](http://gembio.com)