




Storage Controls and Material Specifications

Investigational Microbiota Preparation Receiving

Step 1	Step 2	Step 3
 <p>Check that the WarmMark indicator located on the inside lid of the Styrofoam cooler is active and shows no departure.</p>	 <p>Check that the packaging is intact and that there is no evidence of leakage for each unit. Confirm that the unit ID# on the product labels matches those on the Material Tracking Log.</p>	 <p>Immediately transfer investigational treatments from the insulated shipping container to a freezer. If there are issues with the indicator or packaging, contact OpenBiome.</p>

Investigational Microbiota Preparation Storage & Handling

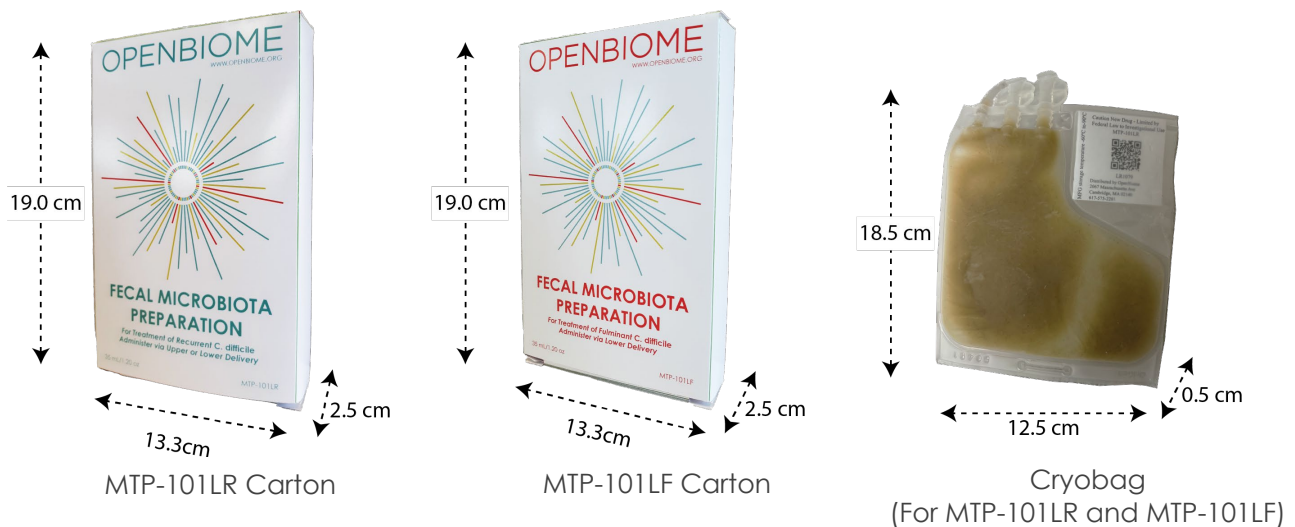
- Each investigational unit is marked with an expiration date of 6 months after shipping, assuming storage in a -20°C freezer.
- Normal temperature fluctuations in freezer temperature of up to 5°C are acceptable. Facilities should use internal site standards to define a temperature excursion, and discard if product has been exposed to a temperature excursion.
- Upon opening, standard protocols for handling biohazardous material should be followed at all times.
- Sterile microbiological technique should be followed when handling investigational material to avoid contamination.
- If investigational treatments need to be destroyed, follow internal protocols for disposal of human stool.

Material Tracking

- The Material Tracking Log should be kept in a safe place and maintained for all units.
- Fill in the **Frozen On Receipt** column upon arrival.
- Fill in remaining columns upon use of treatment.
- The Material Tracking Log must be returned to OpenBiome upon use of all units

MTP-101LR and MTP-101LF

35 mL investigational microbiota preparation for delivery under medical supervision



Box Dimensions	19.0cm x 13.3cm x 2.5cm
Cryobag	18.50cm x 12.50cm x 0.50cm
Port Diameter	3.5 cm
Volume	35 mL
Packaging	35mL Cryobag
Material Cost	\$1695 per unit
Shipping Cost	\$150 per shipment with optional additional fees for expedited shipping
Delivery	Delivered overnight on dry ice by UPS or courier (select locations)
Item Number	MTP-101LR & MTP-101LF

Receiving & Preparation Summary

- May be stored locally for up to 6 months in a standard -20°C laboratory freezer or up to 12 months in a -80°C laboratory freezer.
- Thaw prior to administration by placing the cryobag in an ice bath for at least 30 minutes or until the treatment becomes liquid.
- **DO NOT THAW AT ROOM TEMPERATURE OR IN A WATER BATH**
- Once thawed, the investigational material is ready for immediate administration. After thawing, material may remain at room temperature for up to 4 hours (or refrigerated/on ice for up to 8 hours).
- Samples should never be re-frozen. If thawed and not used within 8 hours, the investigational material should be disposed of, as freeze thaw cycles may compromise viability.

Shipping Summary

- Buyer will cover the \$150 cost of shipping and handling (S&H) per shipment.
- Same-day shipping available on orders submitted before 3 PM EST Monday-Thursday. Additional \$50
- Early-AM Delivery available. 8 AM (standard is 10:30 AM). Additional \$100.

Safety Features

- Temperature monitoring during shipping ensures material remains safely frozen during transit
- Shatter-resistant packaging.