Storage Controls and Material Specifications

**Microbiota Preparation Receiving**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="WarmMark indicator" /></td>
<td><img src="image" alt="FMT Lower Delivery" /></td>
<td><img src="image" alt="FMT Upper Delivery" /></td>
</tr>
<tr>
<td>Check that the WarmMark indicator located on the inside lid of the Styrofoam cooler is active and shows no departure.</td>
<td>Check that the tamper evident packaging is intact for each unit. Do not break seal until directly before use.</td>
<td>Immediately transfer units to a freezer. If there are issues with the indicator or tamper-evident packaging, contact OpenBiome.</td>
</tr>
</tbody>
</table>

**Microbiota Preparation Storage & Handling**

- Each 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 material to avoid contamination.
- If treatments need to be destroyed, follow internal protocols for disposal of human stool.
- All bottles have been cleaned with a sporicidal disinfectant prior to freezing and can be stored in a shared freezer.

**OpenBiome Tracking Program**

- 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 unit and provide FMT Follow-up Form to administering physician.
- The Tracking Log must be returned to OpenBiome upon use of all units or with your next order.
FMT Lower Delivery
250 mL microbiota preparation for delivery via colonoscopy, enema or sigmoidoscopy under medical supervision

<table>
<thead>
<tr>
<th>Box Dimensions</th>
<th>15cm x 7.5cm x 7.5cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle Dimensions</td>
<td>14cm x 6.4cm x 6.4cm</td>
</tr>
<tr>
<td>Mouth Diameter</td>
<td>3.5 cm</td>
</tr>
<tr>
<td>Volume</td>
<td>250 mL</td>
</tr>
<tr>
<td>Packaging</td>
<td>PET Corning Bottle with HDPE screw-cap</td>
</tr>
<tr>
<td>Material Cost</td>
<td>$1695 per unit</td>
</tr>
<tr>
<td>Shipping Cost</td>
<td>Typically $150 per shipment</td>
</tr>
<tr>
<td>Item Number</td>
<td>FMP250</td>
</tr>
</tbody>
</table>

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 using one of the following:
  - 1 hour in a warm water bath
  - 4 hours at room temperature
  - 16 hours in a refrigerator
- Once thawed, the 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 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.
- OpenBiome will cover S&H for orders of 10 units or more.
- Storing multiple units at your facility is the best way to ensure availability for immediate use and also reduce fees.

Safety Features
- Tamper-evident screw cap indicates when a unit has been opened, easing security concerns during storage.
- Temperature monitoring during shipping ensures material remains safely frozen during transit
- Shatter-resistant packaging.
### Box Dimensions
10 cm x 5.7 cm x 5.7 cm

### Bottle Dimensions
6.4 cm x 3.8 cm x 3.8 cm

### Mouth Diameter
2 cm

### Volume
30 mL

### Packaging
PET Corning Bottle with HDPE screw-cap

### Material Cost
$1695 per unit

### Shipping Cost
Typically $150 per shipment

### Delivery
Delivered on dry-ice by overnight courier

### Item Number
FMP30

### 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 using one of the following:
  - 15 minutes in a warm water bath
  - 45 minutes at room temperature
  - 1.5 hours in a refrigerator
- Once thawed, the 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 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.
- OpenBiome will cover S&H for orders of 10 units or more.
- Storing multiple units at your facility is the best way to ensure availability for immediate use and also reduce fees.

### Safety Features
- Tamper-evident screw cap indicates when a unit has been opened, easing security concerns during storage.
- Temperature monitoring during shipping ensures material remains safely frozen during transit.
- Shatter-resistant packaging.

---

**FMT Upper Delivery**
30 mL microbiota preparation for delivery via esophagogastroduodenoscopy (EGD) or naso-enteric tube under medical supervision.
# FMT Capsule DE

30 capsules for oral delivery under medical supervision

<table>
<thead>
<tr>
<th>Box Dimensions</th>
<th>10 cm x 5.7 cm x 5.7 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle Dimensions</td>
<td>9 cm x 5.1 cm</td>
</tr>
<tr>
<td>Mouth Diameter</td>
<td>3.8 cm</td>
</tr>
<tr>
<td>Volume</td>
<td>30 Size 00 capsules</td>
</tr>
<tr>
<td>Packaging</td>
<td>PET Alpha Packaging Bottle with HDPE screw-cap</td>
</tr>
<tr>
<td>Material Cost</td>
<td>$2050 per unit</td>
</tr>
<tr>
<td>Shipping Cost</td>
<td>Typically $150 per shipment</td>
</tr>
<tr>
<td>Delivery</td>
<td>Delivered on dry ice by overnight courier</td>
</tr>
<tr>
<td>Item Number</td>
<td>FMPCapDE</td>
</tr>
</tbody>
</table>

## 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.
- No thawing is required. Patients may begin consuming capsules under direct supervision by a physician once they are removed from the freezer. All 30 FMT Capsule DE pills should be ingested within 90 minutes after removal.
- Bottles come with a child-resistant cap with a pressure sensitive inner seal. Ensure that the seal is not damaged and break seal directly before use.
- Before administering to patient, check capsules for any malformations.
- If all capsules are not consumed during the allotted 90 minutes, the remaining capsules should be discarded.

## Shipping Summary
- Buyer will cover the $150 cost of shipping and handling (S&H) per shipment.
- Storing multiple units at your facility is the best way to ensure availability for immediate use and also reduce fees.

## Safety Features
- Tamper-evident inner seal indicates when a unit has been opened, easing security concerns during storage.
- Temperature monitoring during shipping ensures material remains safely frozen during transit.
- Shatter-resistant packaging.