## Storage Controls and Material Specifications

### Investigational 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="image1" alt="WarmMark indicator" /></td>
<td><img src="image2" alt="Packaging" /></td>
<td><img src="image3" alt="Freezer" /></td>
</tr>
</tbody>
</table>

- **Step 1**: Check that the WarmMark indicator located on the inside lid of the Styrofoam cooler is active and shows no departure.
- **Step 2**: 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.
- **Step 3**: Immediately transfer investigational treatments from the insulated shipping container to a freezer. If there are issues with the indicator or packaging, contact OpenBiome.

### 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

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