

Order Form

Once completed, **email** form to info@openbiome.org OR **fax** to (617) 575-2201

Only registered and approved clinical partners may place an order for investigational FMT.

Directions for completing and submitting a registration form can be found at:

<https://openbiome.org/fmt-access/placing-an-order/#network>

Hospital/Clinic Information		
Name	Partner ID#	
Address		
City, State, Zip		
Shipping Contact		
Name:	Email:	Phone:
Billing Contact		
Name:	Email:	Phone:

Order Information				
Purchase Order Number (Required):				
Item	Description	Price	Quantity	Subtotal
MTP-101LR	35mL Investigational FMT for recurrent <i>C. difficile</i> infection not responsive to standard therapies.	\$1695		
MTP-101LF	35mL Investigational FMT for fulminant <i>C. difficile</i> infection not responsive to standard therapies.	\$1695		
Shipping Fees				
Overnight Air	Standard shipping within 1-2 business days of order processing. Delivery at approximately 10:30 AM. Waived on orders of ten or more.	\$150	X	\$150
Same-Day Shipping	Optional: Available on orders placed Monday-Thursday before 3pm EST.	\$50		
Early-AM delivery	Optional: Delivery by 8AM.	\$100		
Total				

General Information & Policies

- Shipping Policy:** **Standard S&H:** Flat \$150 fee per shipment
- Orders placed Monday-Wednesday will ship in 1-2 business days.
 - Orders placed on Thursday or Friday will be scheduled for delivery the following Tuesday.
 - Material arrives on dry ice in a temperature-monitored container.
 - Estimated local delivery time of 10:30 AM.

- Optional Early-AM Delivery Fee:** \$100 additional fee
- Fee assessed for orders requiring approximate 8 AM delivery.
 - Ships in 1-2 business days.
 - Written confirmation of additional fee must be included with order.

- Optional Same-Day Shipping Fee:** \$50 additional fee
- Fee assessed for orders requiring same-day shipping.
 - Order must be received *before 3 PM ET* Monday-Thursday.
 - Availability not guaranteed.
 - Written confirmation of additional fee must be included with order.

Summary of order and delivery dates

		Order Placed On:				
		Monday	Tuesday	Wednesday	Thursday	Friday
Delivery By:	Standard	Wednesday	Thursday	Friday	Tuesday	Tuesday
	Same-Day Shipping added	Tuesday	Wednesday	Thursday	Friday	Tuesday

Weather notice: OpenBiome will make every effort to process and ship your order for delivery within the estimated delivery date. However, some events beyond OpenBiome's control can occasionally delay a shipment, even an expedited shipment. When forces of nature delay a carrier's delivery of an order, OpenBiome cannot guarantee the arrival date of your order. To reduce any issues caused by a late arrival of treatments, especially during the winter months where weather delays are more frequent, please place your order early to allow extra time for delivery.

- Safety Policy:** All clinicians using material manufactured by the University of Minnesota and distributed by OpenBiome will review the safety information and adverse event reporting requirements provided with each shipment. Should an adverse event occur, a clinician will notify OpenBiome within 24 hours using our online reporting tool at www.openbiome.org/adverse-events. Upon receipt of an adverse event report, an OpenBiome drug safety professional may reach out to the reporting individual to gather more information on the case and determine nextsteps. The information gathered during the investigation will be provided to the University of Minnesota (the manufacturer of the FMT preparation). The University of Minnesota will use the details of your report and any ensuing investigation to determine if there are any additional reporting requirements, which may include submission of the event to the Food and Drug Administration via Form FDA 3500A.

- Usage Policy:** FMT Material manufactured by the University of Minnesota and distributed by OpenBiome is for clinical use only, in accordance with FDA guidelines. Not for resale. FMT Material manufactured by the University of Minnesota and distributed by OpenBiome is for clinical use only, in accordance with FDA guidelines, and has not been approved or licensed by the U.S. Food and Drug Administration or by any other regulatory authority, and it is not commercially available in any market. Not for resale.

- Material Tracking** A Material Tracking Log (MTL) is provided with each shipment to track basic material usage and follow up information. These MTLs are a vital component of safety monitoring, enabling response coordination and proactive system-wide recalls if needed. Partners will submit a completed MTL on all previously shipped units with every new order for OpenBiome material.