



Sutter Roseville Medical Center

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Owner:	<i>Nadera Dashty: Supervisor, Lab Analytic</i>
Policy Area:	<i>Lab - Transfusion Service</i>
References:	
Applicability:	<i>Sutter Roseville Medical Center</i>

Fecal Microbiota Transplant (FMT)

PURPOSE

To provide instructions on how to manage Fecal Microbiota Transplant (FMT) orders from order placement, product reception, preparation, and issuing.

POLICY

- Transfusion Services (TS) will coordinate and manage the processing of FMTs, including ordering, receipt, storage, thawing, and issuing.
 - Notification to the Clinical Research Coordinator, ordering, invoice, payment, and reporting adverse events will be managed by the TS Supervisor. The Laboratory Director will perform these functions in the absence of the TS Supervisor.
- The patient's clinician must place an order for the FMT in Epic prior to or on the day of the procedure. A proposed scheduled date and time for the procedure must be provided to TS upon the initial request.
 - The ordering clinician must be on the approved *OpenBiome Material Tracking Log - Physician Initials*.
 - If the clinician is not on the approved tracking log, notify the TS Supervisor.
 - FMT orders may not populate in Sunquest until the day of procedure.
- Two products are available from OpenBiome and the clinician will need to specify delivery and type of infection in the Epic order or at the time that TS receives the request.
 - MTP-101LR 35mL lower or upper delivery for the treatment of recurrent *C. difficile*.
 - MTP-101LF 35mL lower delivery for the treatment of fulminant *C. difficile*.
- Orders for next day delivery can only be placed Monday - Thursday. FMTs will be kept in TS inventory based on assessment of product use.
 - MTP101LR (upper/lower delivery) for recurrent infections will be kept in TS inventory.
- FMTs are to be stored in a monitored freezer maintained at $\leq -20^{\circ}\text{C}$ and can be kept for up to 6 months (or at -80°C for up to 12 months).
- Endoscopy will notify TS when to begin thawing the FMT. In the event that a FMT is scheduled and a call has not been received one hour prior to the procedure, the CLS will call endoscopy to determine when to begin thawing the FMT.
- Once thawed, the FMT will expire 6 hours from time of thaw while stored at room temperature. In the event that the product is reaching expiration and the clinician has not performed the transplant, consult the Pathologist.
- TS will provide a cannula with the FMT to be used during administration to the patient.

DEFINITION

Fecal Microbiota Transplant: A procedure in which fecal matter (stool) is collected from a tested donor, mixed with saline or another solution, strained, and placed in a patient by colonoscopy, endoscopy, sigmoidoscopy, enema, naso-enteric/naso-gastric tube, or swallowed as a capsule to restore healthy colonic flora in patients with refractory *C. difficile* infections that have failed conventional pharmacological therapy.

EQUIPMENT/SUPPLIES

- Ice and tap water
- Graduated cylinder
- Designated FMT basin
- Plasma overwrap
- Designated quart/ice bucket

PROCEDURE

Initiation of FMT Order

Step	Action
1.	Upon receipt of call or Epic order to TS indicating need for FMT, obtain a prepared <i>FMT Product Record/FMT Issue Form</i> packet from the FMT binder, completing the following fields on the <i>FMT Product Record</i> : <ul style="list-style-type: none">• Patient ID (name and MRN)• Date and time of initial request• Date and time of scheduled procedure (transplantation)• Requesting physician's name• Method of delivery• Tech code of tech receiving request
2.	If available, attach the Epic order to the packet. If the FMT is not to be given on the same day as initiation of order, place the packet in the TS Supervisor's mailbox so that notification to the Clinical Research Coordinator can be completed.

Receiving and Entry of FMT into Sunquest (CLS only)

Step	Action
1.	Remove the FMT from the temperature-controlled packaging immediately upon receipt and confirm that the unit ID matches the product identifier on the <i>OpenBiome Material Tracking Log</i> .
2.	Inspect the FMT and packaging using instructions provided on the <i>Storage Controls and Material Specifications</i> insert to determine if the FMT remained frozen during shipping. <ul style="list-style-type: none">• As long as the FMT is frozen and there is dry ice in the box, it is okay if the indicator shows a color change under the <i>BRIEF</i> indicator.

Receiving and Entry of FMT into Sunquest (CLS only) cont.

Step	Action
3.	<p>Document the following on the <i>FMT Product Record</i>:</p> <ul style="list-style-type: none"> • Unit # • Frozen expiration date • Date and time of delivery/receipt • Specimen frozen? • Temperature tag OK?
4.	<p>Launch Sunquest and select <i>Blood Product Entry</i>. Complete the following fields manually:</p> <ul style="list-style-type: none"> • <i>Supplier</i>: OBM • <i>Component</i>: <ul style="list-style-type: none"> ◦ For 35mL recurrent infection enter <i>FM35R</i> ◦ For 35mL fulminant infection enter <i>FM35F</i> ◦ Container and volume will default in after entering component code • <i>Division #</i>: 00 • <i>Supplier unit #</i>: Enter unit number located on the front of the FMT. <ul style="list-style-type: none"> ◦ Note: Do not include hyphens when entering the unit number. Example: LR1234 ◦ Tab through ABO to expiration information • <i>Expiration date</i>: Date indicated on product label for -20°C storage <ul style="list-style-type: none"> ◦ Expiration time will default to 2359 ◦ Draw date is 6 months prior to expiration date on product label. Draw time will default to 0001 ◦ Receive date/time default to now • <i>Visual inspection</i>: Select PASS or FAIL from drop-down
5.	<p><i>Add</i> FMT to unit summary list, followed by <i>Save</i>.</p>
6.	<p>Prepare a biohazard bag with the following items and store in the designated FMT bin:</p> <ul style="list-style-type: none"> • <i>FMT Follow-Up Form</i> • <i>OpenBiome Clinician's Checklist</i> and accompanying patient information card from OpenBiome • Cannula
7.	<p>Paper clip the <i>FMT Issue Form</i> to the <i>FMT Product Record</i>. If FMT is not needed right away, store FMT in designated drawer of freezer. Place the <i>FMT Product Record/FMT Issue Form</i> packet and the <i>OpenBiome Material Tracking Log</i> in the front of the FMT binder. FMT packets are to be kept in order beginning with the product with the earliest expiration date. Any additional paperwork is to be placed in the TS Supervisor's mailbox.</p> <ul style="list-style-type: none"> • If product is needed, continue to <i>Thawing FMT</i>.

Thawing FMT

Step	Action
1.	Using designated FMT basin, add a single layer of ice to the basin. Using a graduated cylinder, add 800mL of tap water.
2.	Place FMT into a plasma overwrap and lay flat on top of single layer of ice in the basin. Be sure that open end of plasma overwrap is facing up to avoid water/ice entering the bag.
3.	Using the designated FMT quart/ice bucket, fill the basin with 3 quarts of ice.
4.	Set timer for 30 minutes. After 30minutes, determine whether FMT is thawed. Return FMT to basin for 5-10 minute increments until the FMT is thawed. Do not exceed 60 minutes.
5.	Launch Sunquest and select <i>Blood Component Preparation</i> and enter <i>SFMT</i> in the <i>Value</i> field.
6.	Tab through <i>Date</i> to <i>Time</i> and enter time FMT was removed from freezer. Then proceed to tab through <i>Shift</i> and <i>Tech Code</i> , changing as needed, then select <i>Continue</i> .
7.	Under <i>Unit Entry</i> , enter unit number without hyphens in <i>Unit #</i> field (example: LR1234) and tab through <i>Component</i> and <i>Division #</i> . <ul style="list-style-type: none"> Note: If the component does not automatically populate, use the drop-down list to select the correct component.
8.	Under <i>Unit Data</i> , enter the appropriate component code in <i>Component</i> field. Expiration time will default to 6 hours from time of thaw. <ul style="list-style-type: none"> For 35mL recurrent infection enter <i>FM35RT</i> For 35mL fulminant infection enter <i>FM35FT</i>
9.	Review the input and output information for accuracy, then select <i>Save</i> . Select <i>Finish</i> after verifying accuracy in the <i>Preview Output/New Units</i> pop-up window. An additional pop-up window will alert you that a product label will not print, select <i>OK</i> .
10.	Using downtime <i>Revised Expiration</i> label, complete appropriate expiration date and time and place over the frozen expiration on the FMT.
11.	Store FMT on counter at room temperature after thaw.

Allocating FMT

Step	Action
1.	Launch Sunquest and access <i>TFMT</i> order in <i>Blood Order Processing</i> and answer <i>Units Ordered</i> with "1".
2.	Allocate FMT and enter "]" under <i>TS</i> field, followed by <i>Save</i> . <ul style="list-style-type: none"> Note: No unit tag or ISBT label will print.
3.	Print and adhere Epic patient label for the designated patient onto the FMT and call Endoscopy to alert them that the FMT is ready.

Allocating FMT cont.

Step	Action
4.	<p>Store FMT at room temperature with canula and the following documents to be issued with product:</p> <ul style="list-style-type: none"> • <i>FMT Follow-Up Form</i> • <i>OpenBiome Clinician's Checklist</i> pamphlet and accompanying patient informational card from OpenBiome <p>Note: Prepared biohazard bag is located in the designated FMT bin.</p>

Issuing FMT (CLS and SLA)

Step	Action
1.	FMT has no transfuse order associated. Person retrieving FMT must bring an Epic patient label that will be placed on the <i>FMT Issue Form</i> .
2.	<p>When issuing, obtain and complete appropriate fields on the <i>FMT Issue Form</i>. This form takes the place of a transfusion record form for the purposes of issuing.</p> <ul style="list-style-type: none"> • Adhere Epic label provided by retrieving party to the <i>FMT Issue Form</i> • Unit # • Unit expiration (date and time) • Issued & inspected by tech code including date and time • Requesting physician
3.	Launch Sunquest and select <i>Blood Product Issue</i> (BPI) and enter patient MRN into <i>Value</i> field, then <i>Search</i> .
4.	Highlight the patient listing that corresponds to RV (under <i>HID</i>) and enter FMTG into <i>Component</i> field, then select <i>Add</i> followed by <i>Select</i> .
5.	Retrieve thawed FMT and enter unit number into <i>Unit #</i> field, then tab through to check the box next to the appropriate unit, then select <i>Continue</i> .
6.	<p>Compare and read aloud patient identifiers (name, MRN, date of birth) between the following, verifying accuracy:</p> <ul style="list-style-type: none"> • Epic label provided by retrieving party • Epic label placed on thawed FMT • Sunquest BPI screen
7.	Compare and read aloud unit number and expiration date and time of thawed FMT between Sunquest BPI screen and FMT product labels for accuracy.
8.	Ensure thawed FMT passes visual inspection (thawed completely and no leaks), then select <i>Pass All</i> and proceed.
9.	Select <i>Continue</i> , then tab through <i>Issue date</i> , <i>Issue time</i> , and <i>Issue location</i> to default to current date, time, and patient location.

Issuing FMT (CLA and SLA) cont.

Step	Action
10.	Scan the employee badge barcode or manually enter the last name of person accepting unit into <i>Issued to</i> field, then select <i>Save</i> . <ul style="list-style-type: none">• If Sunquest generates a QA failure due to Rh mismatch, override QA with ETC <i>RENOAT</i>.
11.	Provide all accompanying documentation and one cannula with the FMT: <ul style="list-style-type: none">• <i>FMT Follow-Up Form</i>• <i>OpenBiome Clinician's Checklist</i> pamphlet and accompanying patient informational card from OpenBiome
12.	After <i>FMT Issue Form</i> is completed, place in designated transfusion record location. Remaining documentation will be placed in the TS Supervisor's mailbox.

All revision dates:

Attachments

[FMT Follow Up Form.pdf](#)
[FMT Issue Form.pdf](#)
[FMT Product Record.pdf](#)

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