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Owner: *Nadera Poirier: Supervisor,
Laboratory Analytic*

Policy Area: *Lab - Transfusion Service*

References:

Applicability: *Sutter Roseville Medical Center*

Fecal Microbiota Transplant (FMT)

PURPOSE

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

POLICY

- Transfusion Services (TS) will coordinate and manage the processing of FMTs, including ordering, receipt, storage, thawing, and issuing.
 - Ordering, invoice, payment, and reporting adverse events to the supplier will be managed by the TS Supervisor
- The patient's clinician must place an order for FMT in Epic and have a proposed scheduled date and time for the procedure upon order.
 - The ordering clinician must be on the approved *OpenBiome Material Tracking Log - Physician Initials*
 - FMT orders may not populate in Sunquest until the day of procedure. If FMT order is placed in Epic and verified, proceed with processing request.
- 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 verbal request.
 - Lower delivery: Fulminant or recurrent infection
 - Upper delivery
- Orders for next day delivery can only be placed Monday - Thursday. FMTs will be kept in TS inventory based on assessment of product use.
- FMTs are to be stored on a separate shelf from blood products 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 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 FMT.
- Once thawed, 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 of the FMT 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
- Designated quart/ice bucket
- Cannula

PROCEDURE

Initiation of FMT Order

Step:	Action:
1.	Upon receipt of call or Epic order to TS indicating need for FMT, initiate a <i>FMT Product Record</i> form, completing the following fields: <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.	Forward form with completed top fields to the TS Supervisor for order placement and follow-up. <ul style="list-style-type: none">• Laboratory Director will perform these functions in the absence of the TS Supervisor

Receiving and Entry of FMT into Sunquest

Step:	Action:
1.	Remove FMT from 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.
3.	Record whether the FMT was frozen upon receipt on the <i>OpenBiome Material Tracking Log</i> .

4.	<p>If FMT is for a specific patient, retrieve <i>FMT Product Record</i> from designated FMT folder and document the following:</p> <ul style="list-style-type: none"> • Unit # • Frozen expiration date • Date and time of delivery/receipt • Specimen frozen? • Temperature tag OK?
5.	<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. Note: Do not include hyphens when entering the unit number. <ul style="list-style-type: none"> ◦ 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
6.	<p>Add FMT to unit summary list, followed by <i>Save</i>.</p>
7.	<p>If FMT is not needed right away, store in designated drawer of freezer. If product is needed, continue to <i>Thawing FMT</i>.</p>

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 cup, 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 and tab through <i>Component</i> and <i>Division #</i> . 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. <ul style="list-style-type: none"> For 35mL recurrent infection enter <i>FM35RT</i> For 35mL fulminant infection enter <i>FM35FT</i> Expiration time defaults to 6 hours from time of thaw
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 and Issuing 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> . 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.
4.	Store FMT at room temperature with canula and the following documents to be issued with product: <ul style="list-style-type: none"> <i>FMT Follow-Up Form</i> <i>OpenBiome Clinician's Checklist</i> pamphlet and accompanying patient informational card
5.	When issuing, obtain and complete appropriate fields on the <i>FMT Issue Form</i> . <ul style="list-style-type: none"> This form takes the place of a transfusion record form for the purposes of issuing
6.	Refer to SOP <i>Issuing Blood Products and Rhogam Using Blood Product Issue (BPI)</i> and provide all accompanying documentation and one cannula with the FMT. Note: FMT has no transfuse order associated. Person retrieving FMT must bring an Epic patient label that is then placed on the <i>FMT Issue Form</i> . <ul style="list-style-type: none"> If Sunquest generates a QA failure due to Rh mismatch, override QA with ETC <i>RENOAT</i>.
7.	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.

RELATED DOCUMENTS

Issuing Blood Products and Rhogam Using Blood Product Issue (BPI)

All revision dates:

12/19/2022

Attachments

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

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Director, Laboratory Services	12/19/2022
Laboratory Director	Lindsey Westerbeck: Director, Laboratory Services	11/21/2022

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