



Sutter Roseville Medical Center

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Owner:	Nadera Poirier: Spvr, Transfusion Services
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 and issuing.

POLICY

- Transfusion Services will coordinate and manage the processing of FMT products, including ordering, receipt, storage, thawing, and issuing.
 - Ordering, invoice, payment, and reporting adverse events to the supplier will be managed by the Transfusion Services 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.
- FMT products 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 Transfusion Services when to begin thawing of 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 products will expire 4 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 with the Pathologist.

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.

PROCEDURE

Initiation of FMT Order

Step:	Action:
1.	Upon receipt of call to Transfusion Services 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 Transfusion Services Supervisor for order placement and follow-up. <ul style="list-style-type: none">• Laboratory Director will perform these functions in the absence of the Transfusion Services Supervisor.

Receiving and Entry of FMT into Sunquest

Step:	Action:
1.	Remove product 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 product and packaging using instructions provided on the <i>Storing and Administering FMT Microbiota Preparations</i> insert to determine if the product remained frozen during shipping.
3.	Record whether product was frozen upon receipt on the <i>OpenBiome Material Tracking Log</i> .
4.	Retrieve <i>FMT Product Record</i> from FMT folder and document the following: <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 250mL FMT enter <i>FM250</i> ◦ For 30mL FMT enter <i>FM30</i> ◦ Container and volume will default in after entering component code • <i>Division #</i>: 00 • <i>Supplier unit #</i>: Enter unit number found on product. Note: Do not include the 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/time default to 6 months prior to expiration ◦ Receive date/time default to now • <i>Visual inspection</i>: Select PASS or FAIL from drop-down
6.	Add product to unit summary list, followed by <i>Save</i> .
7.	If product is not needed right away, store in designated drawer of freezer. If product is needed, continue to <i>Thawing FMT Product</i> .

Thawing FMT Product

Step:	Action:
1.	<p>Adjust water bath temperature to 30°C:</p> <ul style="list-style-type: none"> • Reset temperature setting to 30°C by holding down the * button until numbers flash • While depressing button, press down arrow until display reads 30.0°C • Discard 3-4 quart sized containers of water from bath • Add ice to bath, mixing (with programmed agitation or manually with quart sized bucket) until temperature has stabilize
2.	<p>Once temperature stabilizes at 30°C, record date and time of initiation of thawing on <i>FMT Product Record</i>.</p> <ul style="list-style-type: none"> • Expiration date and time of thawed product will be based on time removed from freezer.
3.	Double bag product with overwrap, then press <i>Lift Out</i> button to raise basket assembly and place product in basket. Place a security snap over the top of the bag to prevent product from being exposed to water during thaw.
4.	Set cycle to 55 minutes and press <i>Cycle Start</i> to begin thawing.
5.	At the end of 55 minute cycle, examine product for frozen chunks. Return pouch to thaw for 3-10 minutes at a time until product is completely thawed.
6.	Launch Sunquest and select <i>Blood Component Preparation</i> and enter <i>SFMT</i> in the <i>Value</i> field.
7.	Tab through <i>Date to Time</i> and enter time product 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> .
8.	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.

9.	Under <i>Unit Data</i> , enter the appropriate component code in <i>Component</i> field. <ul style="list-style-type: none"> For 250mL FMT enter <i>FM250T</i> For 30mL FMT enter <i>FM30T</i> Expiration time defaults to 4 hours from time of thaw
10.	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> .
11.	Using downtime expiration labels, complete appropriate expiration date and time and place over the frozen expiration on the bottle.
13.	Store product 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 product 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 label for the designated patient onto bottle and call Endoscopy or nursing unit to alert them that product is ready.
4.	Store product at room temperature along with the following documents to be issued with product: <ul style="list-style-type: none"> <i>FMT Follow-Up Form</i> <i>Reporting Adverse Events</i> instructions <i>Clinician Checklist for Reporting Adverse Events to OpenBiome</i> <i>Clinical 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 Using Blood Product Issue Function</i> and provide all accompanying documentation with the product. <ul style="list-style-type: none"> Note: FMT has no transfuse order associated. Person retrieving unit must bring an Epic patient label that is then placed on the <i>FMT Issue Form</i>.
7.	After <i>FMT Issue Form</i> is signed and completed, make a copy and place one with transfuse orders and one with signed transfusion records for reconciliation. Remaining documentation will be placed in the Transfusion Services Supervisor's mailbox.

RELATED DOCUMENTS

Issuing Using Blood Product Issue Function

All revision dates:

Attachments

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

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	pending
Laboratory Director	Lindsey Westerbeck: Dir, Lab	1/20/2022

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