microbiome transmission lab

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mVACSPRO LabVantage Protocol

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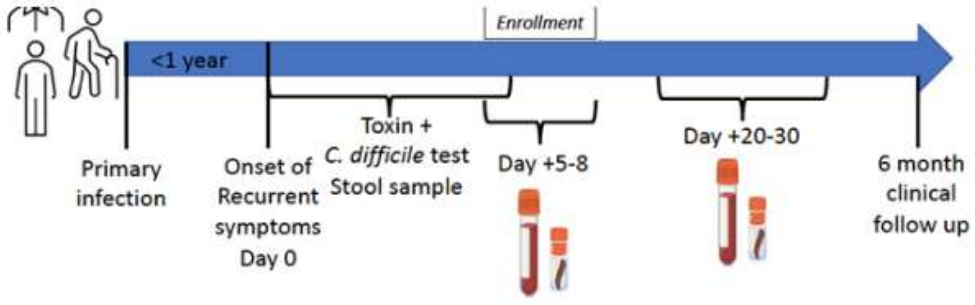
Purpose

Longitudinal cohort study of recurrent *Clostridioides difficile* infection (CDI) in pediatric and adult patients

Study Aims:

- To develop a longitudinal cohort of CDI reoccurrence, for parallel deep microbial and immune profiling, with linage to longitudinal clinical outcomes
- To characterize the clinical outcomes of CDI over 180 days to better understand immunologic differences by age, and their relationship to disease severity and response to treatment

General Study Design:



Scope: This document pertains to the workflow within the Laboratory Inventory Management System (LIMS); the accessioning and creation of specimen labels in LabVantage.

Materials & Equipment

Brady Printer Supplies

- FreezerBondz Ultra-Thin Cryogenic Polyester Laboratory Labels for B33 Printers (Brady Catalog No. B33-179-492)
- B30 Series R6400 Halogen Free Printer Ribbon, Black (Brady Catalog No. B30-R6400)
  If low on supplies, please see Laura before ordering more.

Procedures

A. Accessioning in LabVantage

Accessioning refers to the process of entering the subject and sample information into the LabVantage database. Check your work as you proceed, as an incorrectly accessioned sample can be disposed of, but will clutter reports in perpetuity.

1. Navigate to https://lims.pmacs.upenn.edu/limsprod/logon.jsp and log-in with PMACS credentials.
2. Under the green "Sample Management" menu, select "Receive and Accession Samples."
3. Enter the study ID ("ID_mVACSPRO"), the site ("UPHS"), the cohort ("Participant"), and under "Choose Clinical Events," select "General Collection." **Note**: "Add Duplicant Event" is checked by default; this allows the user to accession multiple samples from the same participant. Ensure it remains checked.
4. Under "Additional Attributes," select the collection date. This should be the date the sample is actually collected, which may be a different date from when the sample is being accessioned.

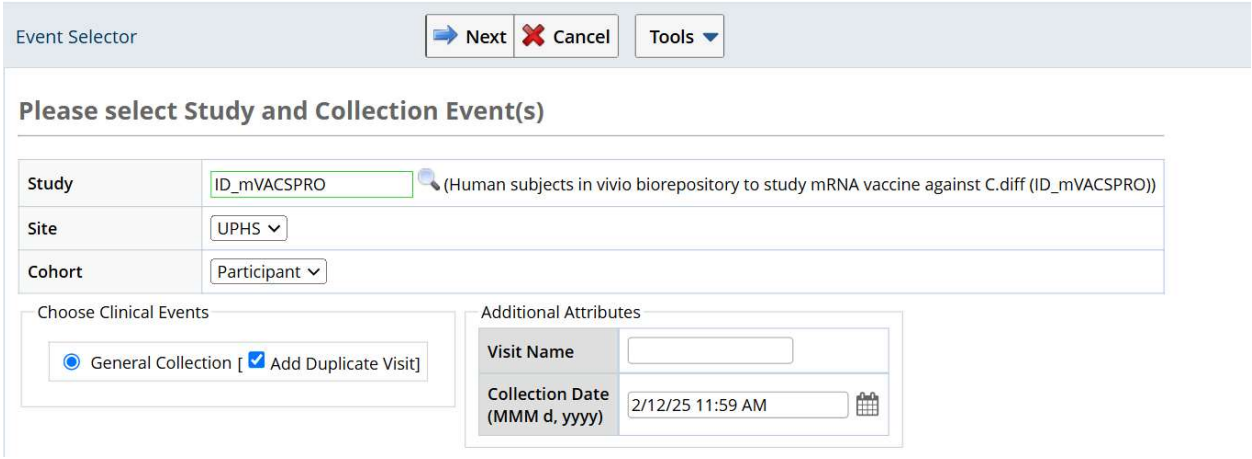


Figure 1. Event Selector menu

5. Once all of the above information has been entered, click "Next."
6. In the resulting window, enter the desired Participant ID in the "Description" field.
   a. **If this is a new participant:**
      i. Click "Add New Subject." Click "Save" followed by "Close" in the pop-up window.

ii. The participant should now be visible in the "Search Results" field and should be checked. Click "Next."

iii. You will be advised that the subject selected is not currently enrolled in the study. Click "Enroll."

b. If this is an existing participant:

i. Click "Search Subject." A list of participants best fitting the search criteria will populate. Find the Subject ID needed, select it and click "Next."

ii. The participant should now be visible in the "Search Results" field and should be checked. Click "Next."

7. The resulting window contains all of the available sample types (Fig. 2). Check the box for each sample type being accessioned.
   a. **If this is a new participant**, enter the Subject ID in the "External Participant ID" box in the upper right-hand corner. The Subject ID and External Participant ID should always match.
   b. Each sample type has a specified "Container" type associated with that sample. **Note**: The label will not contain information pertaining to the container. Remember that Feces = unadulterated stool in a vial, Stool Swab = Copan Fecal Swab and Stool = Zymo Swab.
   c. The collection date for each sample type defaults to what was previous entered. If the specimens have different collection dates, they can be altered at this time.

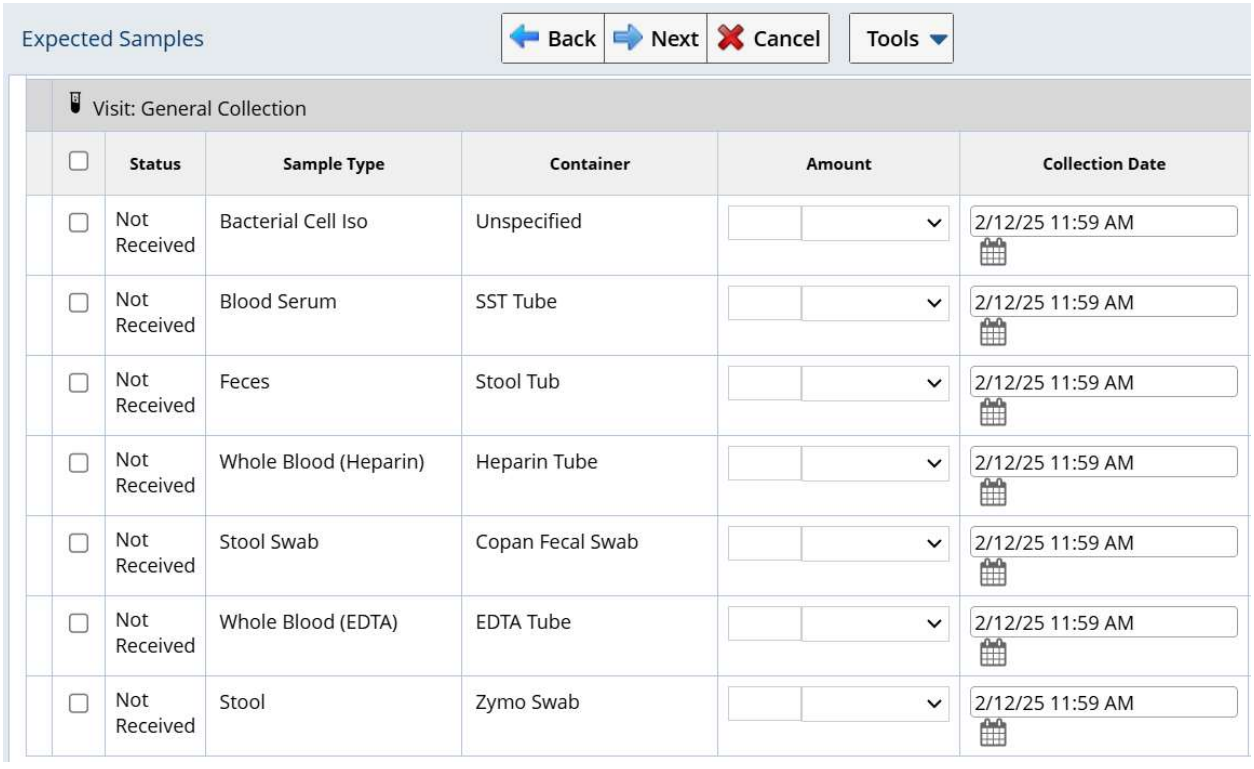
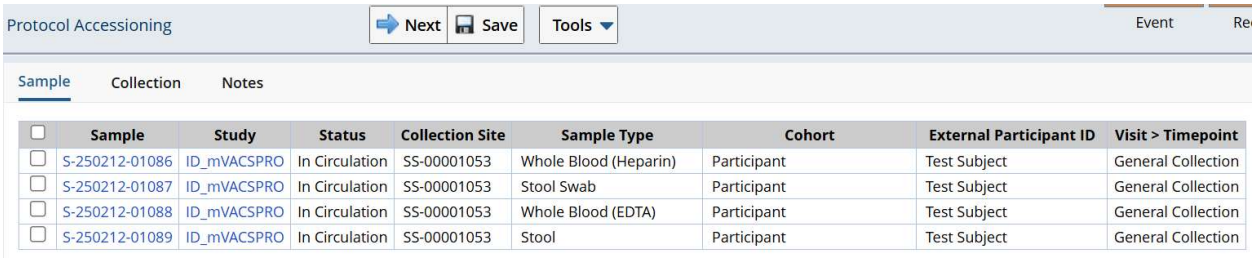


Figure 2. Expected Sample menu.

8. Once the desired samples have been checked, click “Next.”
9. In the resulting window, a summary of your selections will populate along with the Sample Numbers assigned to each (Fig 3).
    a. The Sample Number (S#) assigned to each sample is the ultimate identifier; these are unique to each sample.



Sample	Study	Status	Collection Site	Sample Type	Cohort	External Participant ID	Visit > Timepoint
S-250212-01086	ID_mVACSPRO	In Circulation	SS-00001053	Whole Blood (Heparin)	Participant	Test Subject	General Collection
S-250212-01087	ID_mVACSPRO	In Circulation	SS-00001053	Stool Swab	Participant	Test Subject	General Collection
S-250212-01088	ID_mVACSPRO	In Circulation	SS-00001053	Whole Blood (EDTA)	Participant	Test Subject	General Collection
S-250212-01089	ID_mVACSPRO	In Circulation	SS-00001053	Stool	Participant	Test Subject	General Collection

Figure 3. Protocol Accessioning confirmation window.

10. Click “Next.”
11. In the next window, click “Complete.”
12. You will be auto-routed to the main menu.

B. Printing Labels

[Description of process, if applicable]

1. Under the green “Sample Management” menu, select “Lab Operations Samples.”
2. In the Lab Operations window, select “Created Today” in the drop-down menu of the search bar (Fig 4). This populates a list of all samples created today from across all studies.

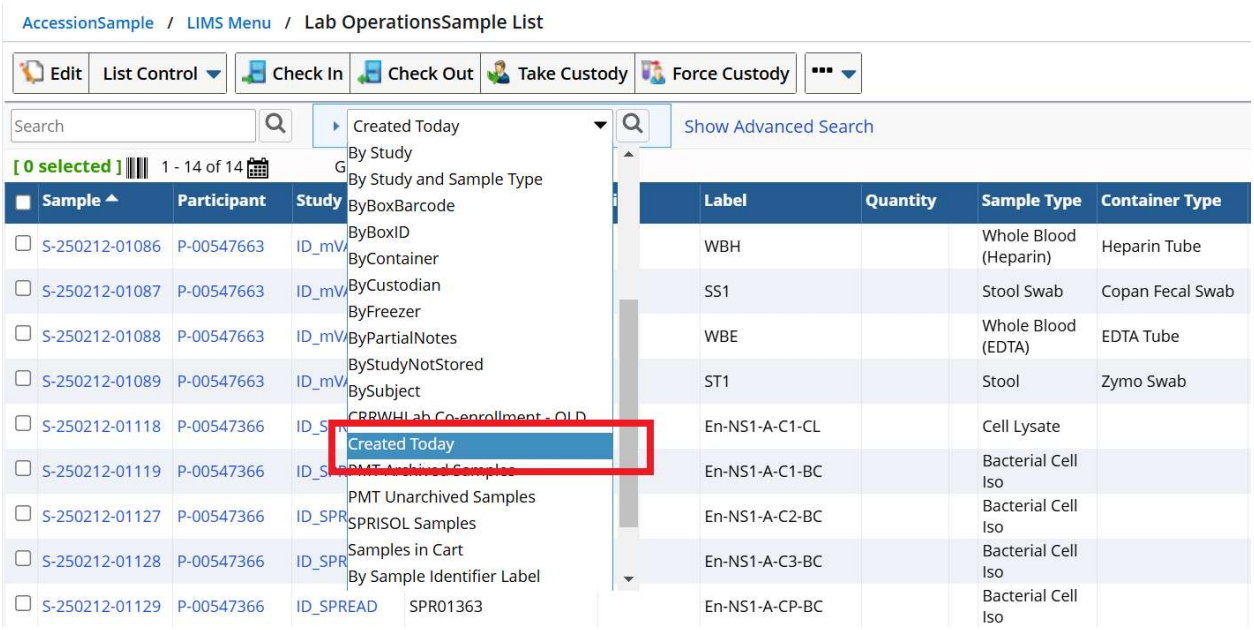


Figure 4. Lab Operations Sample list.

3. Navigate through the list to find and select the desired samples (check box).
4. In the menu bar at the top of the page, select "Print Labels."
5. In the resulting window, make the selections according to Fig 5.

Figure 5. Print Label menu.

6. Click "OK." The desired labels should print.

C. Miscellaneous Tips

1. If you run into issues with LabVantage, please reach out to Laura. If the issue cannot be resolved internally, a ticket can be submitted here: https://helpdesk.pmacs.upenn.edu/
   a. Submit the ticket via the LIMS Help Desk (not PMACS)
2. When printing labels, make sure that the label has printed correctly and hasn't cut off any information. Best practice to avoid this issue is to have the printer adjusted to the following settings. **Note**: these settings reset to default if the printer gets re-booted and will need re-adjusted.
   a. Horizontal offset: 0.04in
   b. Vertical offset: 0.10in
   c. Print speed: 1 ips
   d. Cutting Options: between labels

Change Control

Please note any changes made to the laboratory protocol following study launch by completing the table below. Changes must be approved by the study principal investigator. The SOP should be saved with the date of change saved as part of its file name. Every change should be communicated to lab management.

Date of Change Implementation (MM/DD/YYYY)	Brief Description of Change	Justification for Change	Approved By