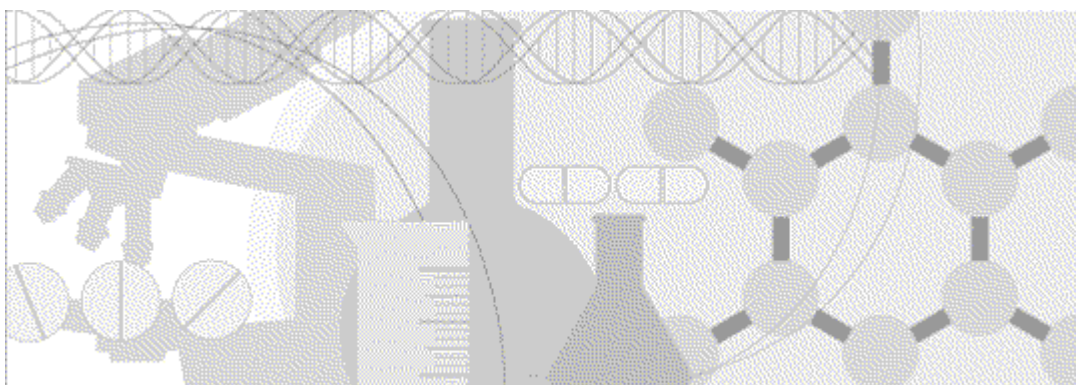


Sample Management Guide

Oracle[®] Health Sciences LabPas
Release 3.1



ORACLE[®]

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About this guide

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Overview of this guide

The LabPas *Sample Management Guide* provides step-by-step instructions for processing and tracking samples in the lab.

Audience

This guide is for everyone who uses the Oracle® Health Sciences LabPas application to manage sample data. This audience includes the study coordinators, study managers, lab managers, and lab technicians who are charged with gathering and reviewing sample data during a clinical trial.

Documentation

All documentation is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>) and the Oracle Technology Network (<http://www.oracle.com/technetwork/documentation>).

All documents may not be updated for every LabPas release. Therefore, the version numbers for the documents in a release may differ. For a complete list of the documents in this LabPas release, their release version numbers, and part numbers, see the *Release Notes*.

Item	Description	Last updated
<i>Release Notes</i>	The <i>Release Notes</i> document presents information about new features, enhancements, and updates for the current release.	3.1
<i>Known Issues</i>	The <i>Known Issues</i> document presents information about known issues for the current release.	3.1
<i>User Guide</i>	The <i>User Guide</i> provides online access to all tasks you can perform from the LabPas application, as well as supporting concepts and reference information. You can access the <i>User Guide</i> from the Help button in the LabPas application.	3.1
<i>Administration Guide</i>	This guide provides a roadmap for configuring and setting up the LabPas application, setting up the LabPas Recruiting module, and viewing and printing reports. This guide contains step-by-step instructions and field definitions you can use to perform tasks such as setting up roles and permissions; setting up various aspects of a facility, such as instruments, samples, and vessels; and configuring the LabPas user interface and messaging.	3.1
<i>Clinical Trial Design and Resource Management Guide</i>	This guide provides a roadmap and step-by-step instructions for a variety of tasks, such as creating clinics, creating studies, planning clinic schedules, planning staff assignments, configuring and setting up the LabPas application, designing a clinical trial and recruitment, and viewing and printing reports and labels.	3.1
<i>Recruiting User Guide</i>	This guide provides step-by-step instructions for setting up and managing recruitment, including adding and contacting volunteers, scheduling, managing advertising campaigns, and performing other related operations. It also includes instructions for screening volunteers in a clinical trial.	3.1
<i>Sample Management Guide</i>	This guide provides step-by-step instructions for processing and tracking samples in the lab.	3.1
<i>Clinical Data Entry Guide</i>	This guide describes how to use the LabPas application to accomplish the typical tasks you would perform while gathering data during a clinical trial. It contains step-by-step instructions and field definitions you can use to perform data entry while capturing data about doses, samples, tests, adverse events, and other observations.	3.1

Item	Description	Last updated
<i>Data Qualification Guide</i>	This guide provides step-by-step instructions for reviewing data that is collected in LabPas CT studies.	3.1
<i>Installation Guide</i>	This guide provides step-by-step instructions for installing the LabPas application.	3.1
<i>Secure Configuration Guide</i>	This guide provides essential secure configuration considerations for the LabPas application.	3.1
<i>Ad Hoc Reports Database Views Guide</i>	This document provides details of the database views used in ad hoc reports. The descriptions include the details of each view as well as corresponding fields where you can verify data.	3.1
<i>Specification for the HL7 Lab Data Interface</i>	This document provides the information that is needed to set up jobs and exchange files automatically between LabPas facilities and the labs that process their samples.	3.1
<i>Specification for the Mortara E-Scribe Interface</i>	This document provides the information needed to set up jobs and import Mortara ECG files.	3.1
<i>Third Party Licenses and Notices</i>	This document includes licenses and notices for third party technology that may be included in or distributed with the LabPas software.	3.1

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info>, or if you are hearing impaired, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs>.

CHAPTER 1

Getting started

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The LabPas application

The LabPas application allows you to create, manage, and automate many tasks involved in early phase clinical trials. The application consists of the following modules.

- **LabPas CT module**—Use the LabPas CT module to establish the elements, settings, and properties on which a study is built. You can set up and configure:
 - Users
 - Facilities
 - Instruments
 - Storage devices
 - Sample and vessel types
 - Test panels
 - Global settings
- **LabPas Resource Management**—Use the LabPas Resource Management module to create and manage clinics, studies, and staff assignments.
- **LabPas Recruiting module**—Use the LabPas Recruiting module to manage volunteer recruitment. You can:
 - Develop study-specific call scripts.
 - Define study inclusion and exclusion criteria.
 - Search the recruiting database for potential volunteers.
 - Receive calls from potential volunteers.
 - Manage advertising campaigns.
 - Schedule outgoing phone calls.
 - Track caller responses.
 - Record volunteer information.
 - Create a schedule of events.
 - Schedule and process screening events.
 - Assign volunteers to studies.
- **LabPas DQ module**—Use the LabPas DQ module to review the data that is collected in LabPas CT studies.

Users, permissions, and roles

A system administrator sets up users' security roles and permissions in the LabPas CT module. Security roles define a specific set of permissions, which authorize users to perform certain functions or to access specific pages and data.

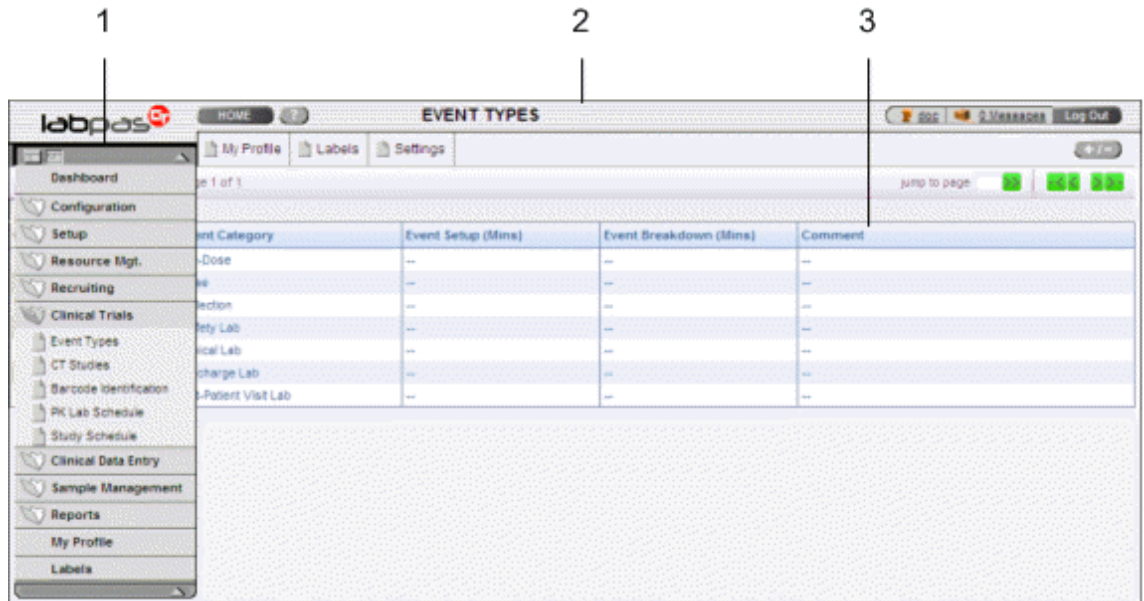
When a system administrator assigns you to a role, you are automatically assigned the permissions associated with that role.

For more information on users, security, and permissions, see *Setting up the LabPas CT module*.

Navigation

Most pages in the LabPas application, including the LabPas Resource Management module and the LabPas Recruiting module, have the following sections:

- 1 **Main menu** (on page 4)
- 2 **Page heading** (on page 5)
- 3 **Data frame** (on page 5)



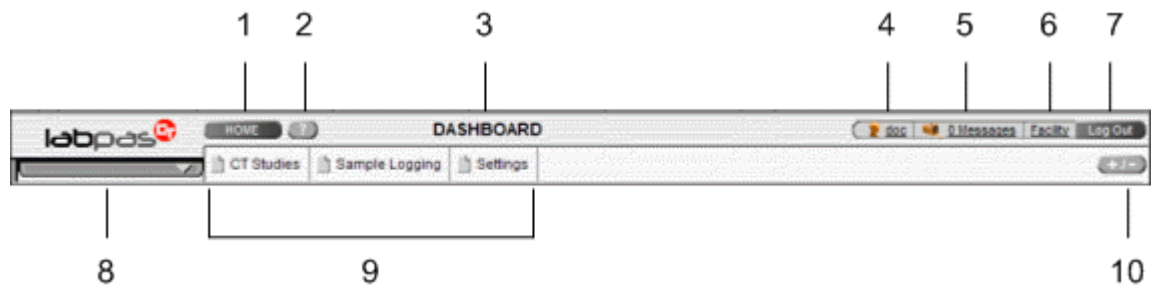
Main menu

The main menu, located in the upper left corner of the page, is a directory of the pages that you access.

- To expand the collapsed main menu, click the down arrow.
The menu automatically collapses a few seconds after you move the cursor off the menu.
- To keep the main menu expanded, click the page icon (🏠).
- To navigate through the application, expand the main menu, click a folder, and select a page in the folder.

Page heading

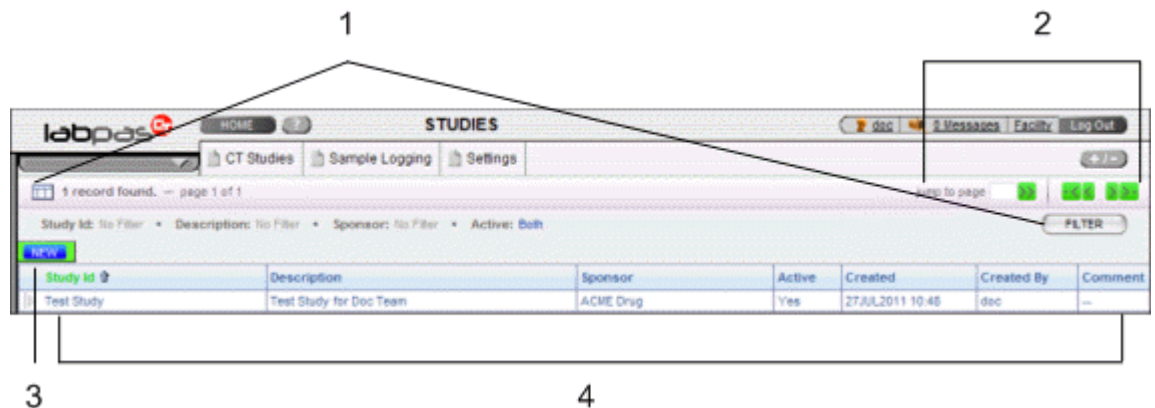
The page heading is similar on all LabPas pages.



- 1—**Home button** Open your home page, as configured on the My Profile page.
- 2—**Help button** Open the *User Guide*, in a separate window, to the section that corresponds to the current page.
- 3—**Page name** Name of the currently selected page.
- 4—**User name** Your user name. Opens your My Profile page.
- 5—**Message indicator** Open the Inbox page in a new window.
- 6—**Facility name** Name of the facility that you are using. Opens the Change Facility dialog box. This link appears only if you have access to more than one facility.
- 7—**Log Out button** End the current session.
- 8—**Main menu bar** Open the main menu, a directory of the pages that you can access.
- 9—**Bookmarks** Shortcuts to menu options. You create your own bookmarks for frequently used options.
- 10—**Bookmarks button** Open a dialog box where you can select and set the order of up to 10 items to be displayed as bookmarks.

Data frame

The data frame contains one or more of the following.



- 1 **Grid tools**—Use the grid setup and filter options to limit and order your selections.
- 2 **Navigation tools**—Navigation arrows at the top of a data frame. Use the arrows to navigate between pages. The arrows are enabled only when more than one page of data is available.
- 3 **Grid function buttons**—Buttons such as ADD, EDIT, and DELETE appear above data grids.
 - Buttons with white backgrounds function only when items in the grid are checked.
 - Buttons with green backgrounds do not require any items to be checked to function.
- 4 **Data grids**—Generally, data grids are tables of information.

Logging on

You access the LabPas application using a web browser. The LabPas Resource Management module and the LabPas Recruiting module are accessed through the LabPas CT module.

- 1 To log on, do one of the following:
 - In the address field of your browser, type `http://<server name>/LabPAS` and press **Enter**.
 - In the address field of your browser, type `http://<server IP address>/LabPAS` and press **Enter**.
 - From the desktop, double-click the shortcut for the LabPas CT module.

The User Logon page appears.

- 2 Type your user ID and password, and click **LOGON**.

Note: The password field is case-sensitive.

Your home page appears.

Note: If the application is not used for a predetermined period of time, your session times out and you must log on again.

Logging off

To exit the LabPas application securely, log off rather than close the web browser. If you do not log off, you might be prevented from logging back on for a short period of time.


If your session times out, log back on and then log off to exit securely from the application.

- In the page header of any page, click **Log Out**.

Changing the contents of the data grid

For each data grid, you can specify the columns to appear in the data frame and the sort order for the data.

To change only the sort order for the currently displayed grid, click the header for any column that displays an up arrow or down arrow.

- 1 Click the grid setup icon ()

The Column Selection dialog box for the current data grid appears.

- 2 Select each column to display.
- 3 Optionally, select the column to sort on and the sort order for the column.
- 4 Click **APPLY**.

Filtering grid data

Use the **FILTER** button to limit the data that appears in the data grid.


- 1 In the top right corner of any page, click **FILTER**.
The Study Selection Criteria dialog box for the current data grid appears.
- 2 Enter your selections and click **APPLY**.

Setting a home page

- 1 In the upper-right corner of any page, click your user name.
The Configure User Profile page appears.
- 2 From the **Home Page** drop-down menu, select a page name.
- 3 Click **UPDATE**.
The selected page is now your home page.

Creating a bookmark

Bookmarks are shortcuts that you create for frequently accessed pages. Your bookmarks appear in the page heading. Bookmarks allow you to access a page with a single click.

- 1 On any page, click the **Bookmark** button () in the page heading
The Bookmarks dialog box appears.
- 2 To select a page to bookmark, click the arrow to the left of any menu item.
The parent menu item opens and displays the sub-menu items. You can expand only one menu item at a time.
- 3 Select one or more menu items.
- 4 Type a sequence number in the field to the right of each item, and click **APPLY**.
You cannot repeat sequence numbers that have already been assigned. For example, you cannot specify that more than one page is sequence number 1.

Deleting a bookmark

- 1 On any page, click the **Bookmark** button in the page heading.
The Bookmarks dialog box appears.
- 2 Click the arrow to the left of any menu item to expand it.
The parent menu item opens and displays the sub-menu items. You can expand only one menu item at a time.
- 3 Deselect the menu items that do not require bookmarks.
- 4 If necessary, enter new sequence numbers for the remaining items.
- 5 Click **APPLY**.

Working with messages

The LabPas message function allows you to communicate within the application with LabPas users.

Reading a message

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Select one or more messages, and click **DISPLAY**.
Message details appear. You can do the following:
 - Reply to the message.
 - Forward the message.
 - Using the navigation arrows, view next and previous selected messages.
- 3 Click **DONE**.
- 4 To close the Inbox, click **DONE**.

Sending a message

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Click **NEW**.
The New Message dialog box appears.
- 3 Fill in the **To** field with one or more user or group names separated by commas, or select the recipients as follows:
 - a Click the ellipsis button (...) next to the **To** field.
The Address Book dialog box appears.
 - b Select one or more users or groups.
 - c Click **SAVE**.
- 4 Fill in the **Subject** and **Message Details** fields.
- 5 Click **SEND**.
- 6 To close the Inbox, click **DONE**.

Deleting a message

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Select one or more messages.
- 3 Click **DELETE**.
A confirmation dialog box appears.
- 4 Click **OK**.
- 5 To close the Inbox, click **DONE**.

Adding a message group

You can set up groups of users as message recipients.

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Click **NEW**.
The New Message dialog box appears.
- 3 Click the ellipsis button (...) next to the **To** field.
The Address Book dialog box appears.
- 4 Click **EDIT GROUPS**.
The Groups dialog box appears.
- 5 Click **NEW**.
The New Group dialog box appears.
- 6 Enter a name for the group and an optional comment, and select the users to include.
- 7 Click **SAVE**.

Editing a message group

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Click **NEW**.
The New Message dialog box appears.
- 3 Click the ellipsis button (...) next to the **To** field.
The Address Book dialog box appears.
- 4 Click **EDIT GROUPS**.
The Groups dialog box appears.
- 5 Select a group and click **EDIT**.

- The Edit Group Details dialog box appears.
- 6 Edit the group information and member list.
- 7 Click **SAVE**.

Deleting a message group

- 1 On any page, click the Messages icon in the page heading.
The Inbox dialog box appears.
- 2 Click **NEW**.
The New Message dialog box appears.
- 3 Click the ellipsis button (...) next to the **To** field.
The Address Book dialog box appears.
- 4 Click **EDIT GROUPS**.
The Groups dialog box appears.
- 5 Select a group and click **DELETE**.
A confirmation message appears.
- 6 Click **OK**.

CHAPTER 2

Logging samples

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Tasks: Sample Logging page

You log the receipt of samples into the lab for processing on the following pages:

- Sample page.
- Sample Logging page.

If CT Sample Logging Required is selected on the Configuration - Settings - Facility page, you must log samples on the Sample Logging page regardless of whether you logged them on the Sample page.

- The LabPas Recruiting module Screening Events page.

Since screening events do not have expected times, the schedule is not adjusted.

- *Logging samples on the Sample Logging page* (on page 19).

Logging samples on the Sample Logging page

Prerequisites:

- At least one study must exist.
 - At least one event must be scheduled in the study.
- 1 From the main menu, select **Sample Management > Sample Logging**.

The Sample Logging page appears.

- 2 Fill in the fields on the page.

Field descriptions for the Sample logging page

Field	Description	Notes
Date Received	(Two fields, one for date and one for time) Date and time when the lab received all samples.	If you edit either field, you must provide a value for both fields. If you do not provide values, the current date and time of the server are used.
Instructions	Logging instructions for the selected row. Instructions are for the study and sample type.	READ-ONLY.

Field	Description	Notes
Vessel Barcode	Vessel barcode for the sample.	<p>REQUIRED.</p> <p>Maximum characters: 30.</p> <p>The sample must be associated with:</p> <ul style="list-style-type: none"> • An active study and group for the current facility. • An active study, if the Vessel Barcode is associated with a LabPas Recruiting module screening sample. • An active study, group, and period, if the Vessel Barcode is associated with a LabPas CT module screening sample. • One of the following: <ul style="list-style-type: none"> ▪ A scheduled event with a status of Not Started or In Progress. ▪ An Adhoc PK or Adhoc Clinical draw event with a status of In Progress.
Study Id	Study ID and description of the study from which all samples in the task originated.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Period	Period from which the sample was collected.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Subject No.	Subject number of the participant from whom the sample was collected.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>

Field	Description	Notes
Screening No.	Screening number of the candidate who is associated with the sample.	<p>REQUIRED.</p> <p>Maximum characters: 30.</p> <p>If the subject number is linked to a screening number, a read-only value appears after you enter a barcode.</p> <p>If the subject number is not linked to a screening number, the value you type is linked to the subject number on the Study - Participants-Subjects page after you save.</p> <p>You cannot edit the sample if it is associated with a LabPas Recruiting module screening event.</p>
Sample Type	Sample type.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Actual Sample Date	<p>Date when the sample was collected.</p> <p>If a sample was recorded on the Sample page, this field contains the date entered on that page and cannot be changed.</p> <p>If a sample was not recorded on the Sample page, this field contains the Expected Date, but you can edit it.</p>	REQUIRED.
Sample Time	<p>Time when the sample was collected.</p> <p>If a sample was recorded on the Sample page, this field contains the time entered on that page and cannot be changed.</p> <p>If a sample was not recorded on the Sample page, this field contains the expected Time, but you can edit it.</p>	<p>REQUIRED.</p> <p>The Sample Time field displays seconds for samples associated with a CT event configured with the Consider Seconds option checked on the CT Studies – Setup – Events screen.</p>

Field	Description	Notes
Comment	Information about the sample. This field contains the comment entered on the Sample page, if it exists. You can overwrite it.	Maximum characters: 80. Required if any of the following is true: <ul style="list-style-type: none"> The Actual Sample Date and Sample Time fall outside the tolerance set for Expected Date and Time. A sample recorded on the SAMPLE page was late. Require Comment is selected on the Settings - Facility page.

Note: If a sample was recorded on the Sample page, all fields except Comment are read-only.

3 Click **SAVE**.

An error occurs if you enter a nonexistent **Screening No.** for a sample associated with a LabPas Recruiting module screening event.

For samples associated with an event with a status of Not Started, if the sample Date and Time do not match the Expected Time of the event, all PK scheduled events (up to the first anchor event) with a status of Not Started and a PK time greater than the PK time of the current event are rescheduled if one of the following conditions applies:

- The Adjust Schedule option for the event associated with the sample is checked, and the Use Tolerance for Adjust option for the event associated with the sample is unchecked.
- Both the Adjust Schedule and Use Tolerance for Adjust options for the event associated with the sample are checked, and the Actual Sample Date and Time field is outside the tolerance for the event.
- The Adjust Schedule (Restricted) option for the event associated with the sample is checked, the Adjusted By option for the event being rescheduled is set to the event associated with the sample, and the Use Tolerance for Adjust option for the event associated with the sample is unchecked.
- The Adjust Schedule (Restricted) and Use Tolerance for Adjust options for the event associated with the sample are checked, the Adjusted By option for the event being rescheduled is set to the event associated with the sample, and the Actual Sample Date and Time field is outside the tolerance for the event.

A sample is considered outside tolerance when either of the following conditions is true:

- The Actual Sample Time is earlier than the Expected Time for the event, and the time by which the sample is early is greater than the Negative Tolerance value configured for the event.
- The Actual Sample Time is later than the Expected Time for the event, and the time by which the sample is late is greater than the Positive Tolerance value configured for the event.

All questions in the form default to a blank value if the Vessel Barcode:

- Is associated with an SR screening or CT clinical event.
- Has an event status of Not Started.
- Is configured with a form on the SR Studies > Setup – Events page, for SR screening events, or the CT Studies > Setup – Events page, for CT clinical events.

When the sample is associated with a CT event that is configured with the Consider Seconds option selected on the CT Studies > Setup – Events page, then:

- Seconds are considered when determining if the sample is outside tolerance.
- Seconds are considered when adjusting the Expected Time for future events that are configured with the Consider Seconds option selected.
- Seconds are not considered when adjusting the Expected Time for future events that are not configured with the Consider Seconds option selected.

If the sample is successfully logged during the save process:

- The Approval Status for the event associated with the sample is set to Not Approved.
- The Monitor Review Status for the event associated with the sample is set to Not Reviewed.

CHAPTER 3

Centrifuging samples

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Tasks: Sample Centrifuge page

On the Sample Centrifuge page, you record centrifuge information for PK samples.

- *Centrifuging samples using the Sample Centrifuge page* (on page 27).

Centrifuging samples using the Sample Centrifuge page

Prerequisites:

- A Centrifuge Instrument barcode must have been defined. Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.
- The Schedule Service for the sample type being processed must be After Centrifuge, After Aliquoting, or (No Selection).

1 From the main menu, select **Sample Management > Sample Centrifuge**.

The Sample Centrifuge page appears.

2 In the **Sample Barcodes** area, type or scan the barcodes of all the samples to centrifuge.

- If a sample has been centrifuged, a message appears. Click **OK** to re-spin the sample.
- If a sample has not been centrifuged and is associated with a study and sample type for which all the fields in the Centrifuge section of the PK Lab Setup page are not blank, a message appears. Click **Continue**. If you cancel, the Sample Barcode field is cleared.

Depending on how your study is set up, the values of some fields in the data area might appear.

3 In the **Instrument Barcode** field, type or scan the barcode of the centrifuge instrument.

4 Fill in the fields.

Field descriptions for the Sample Centrifuge page

Field	Description	Notes
Instructions	Centrifuge instructions for the sample's study and sample type.	<p>READ-ONLY.</p> <p>Instructions appear after you enter a sample barcode. Instructions apply to the field in which the cursor is positioned.</p>
Sample Barcodes	<p>Barcode of the sample to process.</p> <p>You can enter up to 40 barcodes.</p>	<p>Maximum characters: 30.</p> <p>Samples must:</p> <ul style="list-style-type: none"> • Have In Progress statuses. • Be associated with a study, active group, and active period that are all associated with the facility. • Be of the same sample type. • Be from the same study. <p>When you to centrifuge a sample multiple times, a comment is generated.</p>

Field	Description	Notes
Centrifuge Data area	These fields are associated with all sample barcodes in the Sample Barcodes table.	
Instrument Barcode	Barcode of the centrifuge. You can scan or enter a value.	REQUIRED. Maximum characters: 30.
Temperature	Temperature setting for the centrifuge.	REQUIRED. Must be a number from -9999 to 9999. After you provide a sample barcode, a value appears if it was defined in the study in which the sample was collected. You can enter samples from other studies or sample types, if they have the same speed unit, RPM or RCF. If the speeds, temperatures, or duration are different, a warning message appears. You can enter new values, by clearing the Temperature, Speed, and Duration (Min.) fields first. The values that you enter for these fields are applied to all samples that you process together.

Field	Description	Notes
Speed	<p>Speed setting for the centrifuge.</p> <p>After you enter a Sample Barcode, the centrifuge speed unit (either RPM or RCF) appears to the right of the field:</p> <ul style="list-style-type: none"> RPM appears if the RPM option is selected on the Centrifuge Speed field on the CT Studies – Setup – PK Lab page for the study and the sample type associated with the Sample Barcode. RCF appears if the RCF option is selected on the Centrifuge Speed field on the CT Studies – Setup – PK Lab page for the study and the sample type associated with the Sample Barcode. 	<p>REQUIRED.</p> <p>Must be a number from 0 to 9999999999.</p> <p>After you provide a sample barcode, a value appears if it was defined in the study in which the sample was collected.</p> <p>You can enter samples from other studies or sample types, if they have the same speed unit, RPM or RCF. If the speeds, temperatures, or duration are different, a warning message appears. You can enter new values, by clearing the Temperature, Speed, and Duration (Min.) fields first.</p> <p>The values that you enter for these fields are applied to all samples that you process together.</p>

Field	Description	Notes
Duration	<p>Time that samples remain in the centrifuge.</p> <p>This value (in minutes) is added to the Start Date and Start Time to calculate the Centrifuge Out time, which is reported for each sample and is viewable in the following locations:</p> <ul style="list-style-type: none"> • CT Lab Summary Report. • Study - Samples - Samples page. • Exported data from the Study - Events - Data page. 	<p>REQUIRED.</p> <p>Must be a number from 0 to 9999.</p> <p>After you provide a sample barcode, a value appears if it was defined in the study in which the sample was collected.</p> <p>You can enter samples from other studies or sample types, if they have the same speed unit, RPM or RCF. If the speeds, temperatures, or duration are different, a warning message appears. You can enter new values, by clearing the Temperature, Speed, and Duration (Min.) fields first.</p> <p>The values that you enter for these fields are applied to all samples that you process together.</p>
Start Date Start Time	<p>Date and time that you start processing the samples.</p> <p>After you enter an instrument barcode, the current server date and time, adjusted for the facility location as needed, appear.</p> <p>The Start Date and Start Time appear as the Centrifuge In values for each sample in the following locations:</p> <ul style="list-style-type: none"> • Reports. • Study - Samples-Samples page. • Exported data from the Study - Events - Data page. 	<p>REQUIRED. (Both fields)</p>
Comment	<p>Comment about the processing of the samples.</p>	<p>Maximum characters: 80.</p> <p>The comment is saved for all samples processed on this page.</p>

5 Click **SAVE**.

The data is saved and applied to all samples.

The Centrifuge Out time is calculated by adding the Duration (Min.) value to the Start Date and Start Time.

The End Date and Time, which are reported as Centrifuge Out, are calculated by adding the Duration (Min.) value to the Start Date and Start Time.

CHAPTER 4

Separating samples

In this chapter

Tasks: Sample Aliquoting page	34
Separating samples using the Sample Aliquoting page	35

Tasks: Sample Aliquoting page

On the Sample Aliquoting page, you record aliquot information for scheduled and adhoc PK samples and print aliquot labels.

- *Separating samples using the Sample Aliquoting page* (on page 35).

Separating samples using the Sample Aliquoting page

Prerequisites:

- At least one PK Testing event must be scheduled in the study for the sample type being processed.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.
- The Schedule Service for the sample type being processed must be After Centrifuge, After Aliquoting, or (No Selection).

- 1 From the main menu, select **Sample Management > Sample Aliquoting**.

The Sample Aliquoting page appears.

- 2 In the **Sample Barcodes** area, type or scan the barcodes of all the samples to aliquot.

If a sample has not been centrifuged and is associated with a study and sample type for which any of the fields in the Centrifuge section of the PK Lab Setup page are not blank, a message appears. Click **Continue**. If you cancel, the Sample Barcode is cleared.

Depending on how your study is set up, the values of some fields in the data area might appear.

- 3 If labels have not been printed for the aliquot vessels, print the labels. If the study uses vendor-provided transfer tube labels, this option is not available.
 - a Click **LABELS**.
The Print dialog box appears.
 - b Click **OK**.
- 4 Fill in the fields.

Field descriptions for the Sample Aliquoting page

Field	Description	Notes
Sample Barcode	Barcode of the sample to process.	Maximum characters: 30. To be processed, a sample must meet the following requirements: <ul style="list-style-type: none"> • Have an In Progress status. • Be associated with a study, group, and period that are associated with the current facility.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY. A value appears after you enter a valid barcode.
Period	Period from which the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.

Field	Description	Notes
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY. A value appears after you enter a valid barcode.
Sample Type	Sample type.	READ-ONLY. A value appears after you enter a valid barcode.
Instructions	Notes about processing the sample, specific to the sample's study and sample type.	READ-ONLY. If instructions for the sample were set up, they appear after you enter a barcode.

Field	Description	Notes
Aliquot Barcodes	<p>Vessel barcodes of the newly created aliquots. You can scan or type values.</p> <p>The number of fields is determined by the Aliquots Quantity value defined for the sample type.</p> <p>If the aliquot being created replaces a cancelled aliquot and the transfer tube is not vendor labeled, the barcode for the new aliquot must share the same place in the continuing sequence as the cancelled aliquot.</p>	<p>Maximum characters: 30.</p> <p>If a sample has already been aliquoted, the fields are read-only and display the aliquot barcodes previously created.</p> <p>If the study requires global barcode uniqueness, the barcodes must be unique globally.</p> <p>If the study uses vendor-labeled transfer tubes, the barcodes must be unique to the facility.</p> <p>If the study does not use vendor-labeled transfer tubes, the barcodes must be based on the Sample Barcode of the original sample, with a suffix consisting of a dash (-) followed by a capital letter, beginning with A and continuing through the alphabet.</p> <p>If a sample has been aliquoted but has had one or more aliquots cancelled, the Aliquot Barcodes display the existing active and cancelled aliquot barcodes, with the cancelled aliquots in red. All barcodes are disabled. Additional entry fields appear for the cancelled aliquots so you can create replacement aliquots. Replacement aliquot barcodes must be unique, and must correlate directly to the place that the cancelled aliquot initially held in the aliquot sequence.</p> <p>For example, consider three initial aliquots. The 1L-B aliquot, the middle aliquot, was cancelled. The new aliquot should be 1L-E because E holds the same place in the continuing sequence as B. If 1L-A was cancelled, the new aliquot would be 1L-D. If 1L-C had been cancelled, the new aliquot would be 1L-F.</p>
Comment	Comment about the processing of the samples.	<p>Required if the expected number of aliquot barcodes is not entered.</p> <p>Maximum characters: 80.</p>

- 5 Click **SAVE**.

The Expected Time field on aliquot labels includes seconds when the event associated with the sample is configured with the Consider Seconds option selected on the CT Studies – Setup – Events page.

CHAPTER 5

Storing samples

In this chapter

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Storing samples using the Sample Storage page.....	41

Tasks: Sample Storage page

On the Sample Storage page, you record storage information for scheduled and adhoc PK samples and aliquots.

If you process a sample that is already in storage, the sample is moved to the new storage device. The Inventory Storage page is updated with the new location and storage date. The original storage date and time remain unchanged in the CT Sample Inventory and CT PK Sample Processing Log reports.

- *Storing samples using the Sample Storage page.* (on page 41)

Storing samples using the Sample Storage page

Prerequisites:

- At least one PK Testing event must be scheduled in the study for the sample type being processed.
- At least one storage device barcode has been configured.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.
- The Schedule Service for the sample type being processed must be (No Selection).

Scheduled and ad hoc PK samples and aliquots are allowed to be stored.

- 1 From the main menu, select **Sample Management > Sample Storage**.

The Sample Storage page appears.

- 2 In the **Sample Barcodes** fields, enter or scan the barcodes of the samples to store, pressing **Tab** after entering each sample.
 - If a sample has not been centrifuged and is associated with a study and sample type for which any of the fields in the Centrifuge section of the PK Lab Setup page are not blank, a message appears. Click **Continue**. If you click **Cancel**, the Sample Barcode is cleared.
 - If a sample has not been aliquoted and is associated with a study and sample type for which the Quantity field in the Aliquots section of the PK Lab Setup screen is not blank, a message appears. Click **Continue**. If you click **Cancel**, the Sample Barcode is cleared.
 - If the sample is stored for the first time after the Store To time specified for the sample type, a dialog box appears, prompting you to provide a comment. The comment applies only to the sample and overrides the comment in the **Comment** field.

A warning message appears if:

- A valid Sample Barcode is associated with a study and sample type where the Additional Data field in the Sample Information section of the PK Lab Setup page is set to a non-blank value, and
- At least one test from the panel defined in the Additional Data field is not optional and has a blank result value.

If you continue, you are required to enter a comment, which is saved for only the Sample Barcode entered. If you cancel, the Sample Barcode field is cleared.

- 3 Fill in the fields.

Field descriptions for the Sample Storage page

Field	Description	Notes
Instructions	Notes about storage instructions for the sample's study and sample type.	If instructions were set up, they appear after you enter each sample barcode.
Sample Barcodes	Barcode of the sample to store. You can enter up to 40 barcodes.	Maximum characters: 30. All samples are stored at the same location. If a sample is already in storage, it is moved to the storage device that you specify. Samples stored for the first time must be associated with an active group and period. The sample must: <ul style="list-style-type: none"> • Have a status of In Progress or Completed. • Be associated with a study, group, and a period associated with the current facility.
Storage Data area	Information in this area is associated with all sample barcodes.	
Equipment Barcode/Shelf	Barcode of the storage device in which the samples will be stored. Scan or type a value.	REQUIRED. Maximum characters: 32.
Shelf	Two-digit shelf number in the storage device on which the samples will be stored.	READ-ONLY. A value appears after you provide a value for Equipment Barcode/Shelf.
Temperature Class	Temperature class for the storage device.	READ-ONLY. A value appears after you provide a value for Equipment Barcode/Shelf.

Field	Description	Notes
Rack Barcode/Column/ Row	Location in the rack where the samples will be stored, consisting of: <ul style="list-style-type: none"> • A one-digit rack number. • A two-digit column number. • A capital letter for the row. Scan or type a value.	Maximum characters: 32. This field is available only if the storage device supports racks.
Column/Row	Column and row in the rack in which the samples are to be stored.	READ-ONLY. A value appears after you provide a Rack Barcode/Column/Row.
Comment	Comment about the storage of all samples.	Required if a sample is stored for the first time after the Store To time specified for the sample type. Not required for a sample if the Time to Storage field is blank or the Storage section of the Study - PK Lab Setup page has a value of 0.
Temporary Storage	When this field is selected, the Event Status for all sample barcodes is not updated, and the First Storage Date for all samples is not recorded.	This field appears when Allow Temporary Storage in the Temporary Storage section of the Study - Setup - PK Lab is selected. The Allow Temporary Storage field is not displayed when an aliquot barcode is entered. This field is selected by default.

4 Click **SAVE**.

The samples are processed.

The *Inventory Storage page* (on page 83) displays the samples and records the Storage Date as the current date and time of the server, adjusted for the facility location if necessary. Additionally, the storage date and time are recorded in the CT Sample Inventory report (recorded as Freeze Time) and in the CT PK Sample Processing Log report (recorded as Storage Time). The original storage date and time are not changed if an item is being moved from one storage device to another.

Boxes stored record the PK Sample first storage information for any PK samples that have not been stored yet.

The Event Status on the Study - Events - Schedule page for the samples or first aliquots stored changes to Completed.

CHAPTER 6

Packing samples

In this chapter

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Tasks: Sample Packing page

On the Sample Packing page, you record packing information for scheduled samples, ad hoc PK samples, and aliquots. You can also print labels for box barcodes.

- *Packing samples using the Sample Packing page* (on page 47).

Packing samples using the Sample Packing page

Prerequisites:

- At least one PK Testing event must be scheduled in the study for the sample type being processed.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress or Completed. Failed samples are rejected.
- The Schedule Service for the sample type being processed must be (No Selection).
- At least one sample associated with the sample type must have been aliquoted. Cancelled samples are rejected.

- 1 From the main menu, select **Sample Management > Sample Packing**.

The Sample Packing page appears.

- 2 Choose one:

- To pack samples in a new box, click **NEW**.
All data on the page is cleared, and a unique barcode is generated.
- To pack samples in an existing box, type the **Box Barcode**.

- 3 In the **Sample Barcode** field, scan or type the samples to pack, and press **Tab** after each sample.

Field descriptions for the Sample Packing page

Field	Description	Notes
Instructions	Notes about packing the sample.	If instructions for the sample's study and sample type were set up, they appear as you add each sample to the box.
Box Barcode	Barcode of the box into which the samples will be packed. You can use an existing box or generate a new barcode for a new box.	Maximum characters: 30. If you use an existing box, the box: <ul style="list-style-type: none"> • Must belong to an active study. • Must not have been shipped.

Field	Description	Notes
Sample Barcode	<p>Barcode of the sample to add to the box.</p> <p>The sample must:</p> <ul style="list-style-type: none"> • Have a status of In Progress. • Be associated with a study, group, and period that are associated with the same facility as the Box Barcode. • Belong to the same study as the other samples in the box. • Not already have been shipped. • Not already be in the box. <p>If the sample is in another box, the sample is removed from the box and added to the current box.</p>	<p>Maximum characters: 30.</p> <ul style="list-style-type: none"> • If multiple aliquots are not allowed in a box, you can add to the box only samples with the same aliquot suffix as the samples in the box. • If multiple time points are not allowed in a box, samples for the box must be associated with the same time point as the samples that are already in the box. • If multiple subjects are not allowed in a box, samples for the box must be from the same subject as the samples already in the box.
Sample table	Samples are listed in the order that you add them to the box. All fields are read-only.	
Vessel Barcode	Vessel barcode for the sample.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.
Study Id	Study ID and description of the study from which all samples in the task originated.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.
Subject No.	Subject number of the participant from whom the sample was collected.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.
Screening No.	Screening number of the participant from whom the sample was collected.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.

Field	Description	Notes
Sample Id	Identifier assigned to the sample when the schedule was created.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.
Sample Type	Sample type.	After you enter a valid box barcode, a value relating to the samples packaged in the box appears. If the box is empty, a value does not appear.

Valid samples are added to the sample table.

If a sample has not been centrifuged and is associated with a study and sample type for which any of the fields in the Centrifuge section of the PK Lab Setup page are not blank, a message appears. Click **Continue**. If you cancel, the Sample Barcode is cleared.

If a sample has not been aliquoted and is associated with a study and sample type for which the Quantity field in the Aliquots section of the PK Lab Setup page is blank, a message appears. Click **Continue**. If you cancel, the Sample Barcode is cleared.

- 4 To remove a sample from the box, click the **X** button to the left of the sample in the sample table.
- 5 To print a box label:
 - a Click **PRINT**.
The Print dialog box appears.
 - b Click **OK**.
If the box contains at least one sample, the label includes the study, period, and group.
- 6 After you finish entering packing details, leave the page.

The data is saved.

Samples that you processed are available for use on another processing page.

CHAPTER 7

Shipping samples

In this chapter

Tasks: Sample Shipping page	52
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Tasks: Sample Shipping page

On the Sample Shipping page, you record shipping information for scheduled samples, ad hoc PK samples, and aliquots.

- *Shipping samples using the Sample Shipping page* (on page 53).

Shipping samples using the Sample Shipping page

Prerequisites:

- At least one PK Testing event must be scheduled in the study for the sample type being processed.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.
- The Schedule Service for the sample type being processed must be (No Selection).
- At least one box barcode must exist.
- At least one address must be set up on the Study - Setup - Addresses page for the study associated with the box barcode.

Boxes packed with scheduled and ad hoc PK sample and aliquots can be shipped.

If you leave the page without saving and return to the page, data that you entered is still available.

You can save the page with a blank shipment date, and then print the shipping report.

- 1 From the main menu, select **Sample Management > Sample Shipping**.

The Sample Shipping page appears.

- 2 In the **Carton No.** and **Box Barcode** fields, scan or type the cartons and boxes to ship, pressing **Tab** after entering each field.

Information about the contents of the box appears in the table.

- 3 Provide a shipping address:

- a Click **SHIP ADDRESS**.

The Shipping Address Lookup dialog box appears, displaying all addresses created for the study that is associated with the first box barcode.

- b Select an address.

The address appears in the Shipping Address field.

- 4 Fill in the fields.

Field descriptions for the Sample Shipping page

Field	Description	Notes
Instructions	Notes about processing tasks of this type. If shipping instructions for the associated study and sample type were created, they appear after you enter a box barcode.	Instructions appear only when a box contains a single sample type.
Shipping Address	Shipping address for the shipment.	

Field	Description	Notes
Shipment Date	Date and time of shipment.	Default: Blank. If you enter a date, you must also enter a time. Date and time cannot be in the future.
Carrier	Name of the company that is shipping the shipment.	REQUIRED. This information is for reference only.
Tracking No.	Carrier's tracking number for the shipment.	
Documents Enclosed	When selected, documents are included with the shipment.	This information is for reference only.
Carton No.	Carton number into which the box is loaded.	REQUIRED. Must be a number from 1 to 999. This information is for reference only.
Box Barcode	Barcode of the box into which the samples will be packed.	REQUIRED. Maximum characters: 30. All boxes for the shipment must belong to the same study. The box must: <ul style="list-style-type: none"> • Be associated with the current facility. • Belong to an active study. • Not already be in the shipment. • Not already have been shipped.
Table	Each row contains data about a subject. Values appear after you enter a carton number and box barcode.	
Carton No.	Carton number into which the box is loaded.	READ-ONLY.
Box Barcode	Barcode of the box into which the samples will be packed.	READ-ONLY.

Field	Description	Notes
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.

- 5 To remove a box from the shipment, click the **X** button to the left of its row.
- 6 To clear the shipping address, click **CLEAR ADDRESS**.
If there are no boxes in the shipment, the study allocation is also cleared, so you can start a shipment from a different study.
- 7 Click **SAVE**.
 - If the Shipment Date is blank, a warning appears. You can save the shipment with a blank shipment date, or Cancel.
 - Samples that you processed are available for use on another processing page.

CHAPTER 8

Recording information about a sample

In this chapter

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Tasks: Sample Information page

On the Sample Information page, you record data for PK Testing samples, including additional data for urine and feces data and void information.

As you enter each sample, the tests fields for the Test Panel appear for the sample's study and sample type. Test panel data is validated according to the rules defined on the Tests page.

- *Recording information about a sample* (on page 59).
- *Editing sample information* (on page 62).

Recording information about a sample

Prerequisites:

- At least one study must exist.
- A least one PK Sample Type must be linked to a test panel on the Study - Setup - PK Lab page.
- At least one PK Testing event must have been set up for a study.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.

- 1 From the main menu, select **Sample Management > Sample Information**.

The Sample Information page appears.

- 2 In the **Vessel Barcode** field, scan or type a sample's barcode, and press **Tab**.

The test panel fields that appear depend on the Test type for each test in the panel.

Note: The edit field that appears for the Long Text type accepts up to 1000 characters.

Any samples associated with the Vessel Barcode from the Sample Pooling page appear in the Pooled Samples Table.

- 3 Fill in the fields. In the test value fields, enter test data as it is collected.

Field descriptions for the Sample Information page

Field	Description	Notes
Vessel Barcode	Vessel barcode for the sample.	<p>Maximum characters: 30.</p> <p>The barcode must:</p> <ul style="list-style-type: none"> • Be associated with a study, active group, and active period for the current facility. • Belong to a PK sample with a status of In Progress. <p>The field accepts barcodes associated with parent samples, as well as barcodes associated with parent sample aliquots. If an aliquot barcode is entered, the data associated with the parent sample appears and all changes are saved to the parent sample.</p>

Field	Description	Notes
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY. A value appears after you enter a valid barcode.
Period	Period from which the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY. A value appears after you enter a valid barcode.
Sample Type	Sample type.	READ-ONLY. A value appears after you enter a valid barcode.
Instructions	Instructions for the sample and sample type associated with the barcode. If instructions were created, they appear after you enter a barcode.	READ-ONLY.
Comment	Comment about the processing of the samples.	Maximum characters: 80. The comment is saved with the sample, not with individual result records.
Start Date/Time	Date and time that the testing begins.	
End Date/Time	Date and time that the testing ends.	
Pooled Samples	This table appears when the Vessel Barcode from the Sample Pooling page has associated samples. The table displays the samples.	
Vessel Barcode	Vessel barcode for the sample.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY.

Field	Description	Notes
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY.
Start Date	Date that the testing begins.	READ-ONLY.
End Date	Date that the testing ends.	READ-ONLY.
Comment	Comment about the processing of the samples.	READ-ONLY. The comment is saved with the sample, not with individual result records.

4 Click **SAVE**.

If any entries violate edit checks, the following actions occur:

- **Warn** or **Warn and Alert** action—A warning message appears.
- **Alert** or **Warn and Alert** action—The test in violation is flagged with an alert on the Study - Labs page.
- **Prevent** action—A warning message appears, and you cannot save until you correct the results that violated the edit check.

The Event Status on the Study - Events - Schedule page for the sample changes to Completed.

If the sample Approval Status was set to Approved, it changes to Not Approved. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment stating approved data has changed is saved with the audit record.

If the Monitor Review Status of the sample was set to Reviewed, it changes to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment stating reviewed data has changed is saved with the audit record.

Editing sample information

- 1 From the main menu, select **Sample Management > Sample Information**.

The Sample Information page appears.

- 2 In the **Vessel Barcode** field, type or scan a sample's barcode, and press **Tab**.

Information associated with the sample appears.

Fields for the test panel appear.

Any samples associated with the Vessel Barcode from the Sample Pooling page appear in the Pooled Samples Table.

- 3 Fill in the fields.

Field descriptions for the Sample Information page

Field	Description	Notes
Vessel Barcode	Vessel barcode for the sample.	Maximum characters: 30. The barcode must: <ul style="list-style-type: none"> • Be associated with a study, active group, and active period for the current facility. • Belong to a PK sample with a status of In Progress.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY. A value appears after you enter a valid barcode.
Period	Period from which the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a valid barcode.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY. A value appears after you enter a valid barcode.

Field	Description	Notes
Sample Type	Sample type.	READ-ONLY. A value appears after you enter a valid barcode.
Instructions	Instructions for the sample and sample type associated with the barcode. If instructions were created, they appear after you enter a barcode.	READ-ONLY.
Comment	Comment about the processing of the samples.	Maximum characters: 80.
Start Date/Time	Date and time that the testing begins.	
End Date/Time	Date and time that the testing ends.	
Pooled Samples	This table appears when the Vessel Barcode from the Sample Pooling page has associated samples. The table displays the samples.	
Vessel Barcode	Vessel barcode for the sample.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY.
Start Date	Date that the testing begins.	READ-ONLY.
End Date	Date that the testing ends.	READ-ONLY.
Comment	Comment about the processing of the samples.	READ-ONLY.

4 Click **SAVE**.

If any entries violate edit checks, the following actions occur:

- **Warn** or **Warn and Alert** action—A warning message appears.
- **Alert** or **Warn and Alert** action—The test in violation is flagged with an alert on the Study - Labs page.
- **Prevent** action—A warning message appears, and you cannot save until you correct the results that violated the edit check.

If the Vessel Barcode is Approved or Reviewed, the Review Status for the sample changes to Revised.

The Event Status on the Study - Events - Schedule page for the sample changes to Completed.

CHAPTER 9

Associating a sample with a pooled sample

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Tasks: Sample Pooling page

On the Sample Pooling page, you associate PK samples with a scheduled PK sample.

- *Associating a sample with a pooled sample* (on page 67).
- *Removing a sample association* (on page 71).

Associating a sample with a pooled sample

Prerequisites:

- At least one PK Testing event must have been set up for a study.
- Samples must have been logged on the Sample Logging page, the Sample page, or both.
- Samples must have a status of In Progress.

A sample barcode is considered to be pooled into the correct pooling interval when the following requirements are met:

- The Actual Sample Date of the sample barcode is the same as or later than the Expected Time of the pool barcode.
- The Actual Sample Date of the sample barcode is earlier than the Expected Time of the next scheduled event associated with the same sample type as the pool barcode, or the pool barcode is the last scheduled event for the sample type.

- 1 From the main menu, select **Sample Management > Sample Pooling**.

The Sample Pooling page appears.

- 2 In the **Pool Barcode** field, type or scan a sample's barcode, and press **Tab**.

Field descriptions for the Sample Pooling page

Field	Description	Notes
Pool Barcode	Barcode of the sample to add to the pool. Scan or type a value.	Maximum characters: 30. The sample must: <ul style="list-style-type: none"> • Be associated with an active study, active group, and active period for the current facility. • Belong to a scheduled PK Testing sample with a status of In Progress • Be in an active study.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY. A value appears after you enter a pool barcode.
Period	Period from which the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.

Field	Description	Notes
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY. A value appears after you enter a pool barcode.
Sample Type	Sample type.	READ-ONLY. A value appears after you enter a pool barcode.
Instructions	Pooling instructions for the study and sample type associated with the Pool Barcode. Instructions appear after you enter a barcode.	READ-ONLY.
Sample Barcode	Barcode of the PK Testing sample to add to the pool.	This field is available after you enter a Pool Barcode. The sample must: <ul style="list-style-type: none"> • Be associated with a study, active group, and active period for the current facility. • Not already be in the pool. • Belong to the same study as the Pool Barcode sample. • Belong to the same subject and candidate as the pooled sample. • Belong to the same sample type as the first sample in the pool.
Pooled Samples	The columns that appear are determined by the test panel selected on the Study - Setup - PK Lab page for the sample type of the first sample in the pool.	
Vessel Barcode	Vessel barcode for a sample that has been added to the pool.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.

Field	Description	Notes
Start Date	Date you started processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
End Date	Date you stop processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
Comment	Comment about the processing of the samples.	READ-ONLY.
Unpooled Samples	This table displays samples that have not been pooled.	If a sample type is configured in the Pool Sample Type field on the Study - PK Lab Setup page for the study and sample type associated with the pool barcode, this table shows only the samples associated with the specified sample type.
Vessel Barcode	Vessel barcode for a sample that you can add to the pool.	READ-ONLY.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.
Start Date	Date you started processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
End Date	Date you stopped processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
Comment	Comment about the processing of the samples.	READ-ONLY.

The Sample Barcode field is enabled. The Unpooled Samples table displays samples that can be but have not yet been included in the current pool.

- 3 In the **Sample Barcode** field, type or scan a barcode, and press **Tab**.

The Pooled Samples table displays the vessel barcode, and the sample is associated with the pooled sample. The vessel barcode is removed from the Unpooled Samples table.

The Event Status for the sample barcode is changed to Completed.

If you add a Sample Barcode to the incorrect pooling interval, a warning message appears. You can add the sample to the pool or cancel.

Removing a sample association

- 1 From the main menu, select **Sample Management > Sample Pooling**.

The Sample Pooling page appears.

- 2 In the **Pool Barcode** field, type or scan a sample's barcode, and press **Tab**.

Field descriptions for the Sample Pooling page

Field	Description	Notes
Pool Barcode	Barcode of the sample to add to the pool. Scan or type a value.	Maximum characters: 30. The sample must: <ul style="list-style-type: none"> • Be associated with an active study, active group, and active period for the current facility. • Belong to a scheduled PK Testing sample with a status of In Progress • Be in an active study.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY. A value appears after you enter a pool barcode.
Period	Period from which the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.
Subject No.	Subject number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.
Screening No.	Screening number of the participant from whom the sample was collected.	READ-ONLY. A value appears after you enter a pool barcode.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY. A value appears after you enter a pool barcode.
Sample Type	Sample type.	READ-ONLY. A value appears after you enter a pool barcode.

Field	Description	Notes
Instructions	Pooling instructions for the study and sample type associated with the Pool Barcode. Instructions appear after you enter a barcode.	READ-ONLY.
Sample Barcode	Barcode of the PK Testing sample to add to the pool.	This field is available after you enter a Pool Barcode. The sample must: <ul style="list-style-type: none"> • Be associated with a study, active group, and active period for the current facility. • Not already be in the pool. • Belong to the same study as the Pool Barcode sample. • Belong to the same subject and candidate as the pooled sample. • Belong to the same sample type as the first sample in the pool.
Pooled Samples	The columns that appear are determined by the test panel selected on the Study - Setup - PK Lab page for the sample type of the first sample in the pool.	
Vessel Barcode	Vessel barcode for a sample that has been added to the pool.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.
Start Date	Date you started processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
End Date	Date you stop processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.

Field	Description	Notes
Comment	Comment about the processing of the samples.	READ-ONLY.
Unpooled Samples	This table displays samples that have not been pooled.	If a sample type is configured in the Pool Sample Type field on the Study - PK Lab Setup page for the study and sample type associated with the pool barcode, this table shows only the samples associated with the specified sample type.
Vessel Barcode	Vessel barcode for a sample that you can add to the pool.	READ-ONLY.
Time Point	Time point of the event in which the sample was taken.	READ-ONLY.
Sample Type	Sample type.	READ-ONLY.
Start Date	Date you started processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
End Date	Date you stopped processing the sample. The current server date, adjusted for the facility location if necessary, appears by default, but you can modify the value.	READ-ONLY.
Comment	Comment about the processing of the samples.	READ-ONLY.

The Pooled Samples table displays samples associated with the pooled sample.

- 3 In the Pooled Samples table, click the **X** button to the left of the sample to delete. A dialog box appears, prompting you to confirm the removal.
- 4 Click **OK**.

The sample is removed from the Pooled Samples table and is added to the Unpooled Samples table.

The Event Status for the sample barcode changes to In Progress.

If the Approval Status of the sample removed from the pool was set to Approved, it changes to Not Approved. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment stating approved data has changed is saved with the audit record.

If the Monitor Review Status of the sample removed from the pool was set to Reviewed, it changes to Not Reviewed. An entry will be recorded in the CT Change Log with a source of Study Data Approval. A comment stating reviewed data has changed is saved with the audit record.

CHAPTER 10

Recording test results for a sample

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Tasks: Sample Results page

On the Sample Results page, you record clinical test results for:

- Scheduled clinical testing samples.
- Scheduled clinical testing ad hoc samples.
- Scheduled clinical testing samples from LabPas Recruiting screening events.

The results appear on the Study - Results page for the study that is associated with the sample. If the sample is associated with a repeat LabPas Recruiting module screening event, the tests that are not repeating are disabled on the SR Studies - Labs page.

Test results appear by panel in the Results table. The first panel appears by default.

As you enter or edit test results, the results are compared to the reference range or reference value defined for the test on the Study - Setup - Panels page. If a test has demographic reference ranges defined and the gender or age for the participant is known, the appropriate range from the demographic list is used. If a result violates a reference range, a warning appears, displaying the expected result for the test and the Instructions for the test setup on the Tests page.

- ***Recording test results for a sample*** (on page 77).

Recording test results for a sample

Prerequisites:

- At least one Clinical Testing event must be scheduled in the study.
- Samples must have a status of In Progress.

- 1 From the main menu, select **Sample Management > Sample Results**.

The Sample Results page appears.

- 2 In the **Sample Barcode** field, type or scan the barcode of a sample, and press **Tab**.

Information about the sample appears in the read-only fields.

If results have been entered for any tests on this page or the Study - Results page, the results appear and are editable.

- 3 Fill in the fields.

Field descriptions for the Sample Results page

Field	Description	Notes
Sample Barcode	Barcode of a clinical sample.	<p>The sample must be associated with:</p> <ul style="list-style-type: none"> • An active study and group for the current facility. • An active study, if the Sample Barcode is associated with a LabPas Recruiting module screening sample. • An active study, group, and period if the Sample Barcode is associated with a LabPas CT module screening sample. <p>The sample must have a status of In Progress.</p>
Study Id	Study ID and description of the study from which all samples in the task originated.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Adhoc	<ul style="list-style-type: none"> • Yes—The sample was obtained from a nonscheduled event. • No—The sample was obtained from a scheduled event. 	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>

Field	Description	Notes
Screening		<p>Displayed when Screening is set to Yes.</p> <p>The Time Point and Subject No. fields are blank when this field is displayed.</p>
Sample Id	Identifier assigned to the sample when the schedule was created.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Actual Sample Date	Date the sample was obtained.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p> <p>The Actual Sample Date field displays seconds for samples associated with CT study events if the Consider Seconds option is selected on the CT Studies – Setup – Events page.</p>
Sample Type	Sample type.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Screening No.	Screening number of the participant from whom the sample was collected.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Subject No.	Subject number of the participant from whom the sample was collected.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Time Point	Time point of the event in which the sample was taken.	<p>READ-ONLY.</p> <p>A value appears after you enter a valid barcode.</p>
Lab Instructions	<p>Lab instructions for the study and sample type associated with the sample.</p> <p>Instructions appear after you enter a barcode.</p>	READ-ONLY.

Field	Description	Notes
Results table	Any test results that have been entered or imported for the sample on the Study - Results page appear. Otherwise, all fields are blank.	To appear on this page, an event must have been processed through Sample Logging, or through the Sample or Adhoc Lab pages, if CT sample logging is not required. Panels that include tests with alerts are red.
Test	Name of the test. Tests with alerts are red.	READ-ONLY.
Optional	Yes —Test is optional in this study. No —Test is required in this study.	If Optional is selected and the test was not performed, the test is listed in the table with a blank result field.
Result	Result of the test or tests.	REQUIRED. The fields that appear in the Result column depend on the associated test type. Note: The edit field associated with the Long Text lookup button accepts up to 1000 characters.

Field	Description	Notes
Ref. Range	The reference range of the result record.	<p>If a result record exists for a test, then the Ref. Range field displays the reference range stored with that result record.</p> <p>If a result record does not exist for a test, then the Ref. Range field displays the reference range defined for that test on the CT Studies – Setup – Panels page (if the sample is associated with a CT clinical event) or the SR Studies – Setup – Panels page (if the sample is associated with an SR screening event).</p> <p>Any manual edit to a result is checked against the reference range defined for that test on the CT Studies – Setup – Panels page (if the sample is associated with a CT clinical event) or the SR Studies – Setup – Panels page (if the sample is associated with an SR screening event).</p>
Performed By	Person who obtained the results.	
Date	Date and time the results were obtained.	<p>REQUIRED.</p> <p>You must provide both a date and a time.</p>
Alert	If a test has an alert, the alert code and description appear.	READ-ONLY.
Source	Source of the test result data.	<p>READ-ONLY</p> <p>If the source is other than blank or LabPas and the Editable field for the test is not checked on the CT Studies – Setup – Panels page (if the sample is associated with a CT clinical event) or the SR Studies – Setup – Panels page (if the sample is associated with an SR screening event), all fields except Clin. Sig. and Comment are read-only.</p>

Field	Description	Notes
Clin. Sig.	Whether results of the test are marked as clinically significant.	
Comment	Note about one, several, or all tests.	If one or more results are not entered, you must enter a comment for them.

Change Comment

Field	Description	Notes
Comment	Comment saved with the change into the CT Change Log.	REQUIRED.

Note: You are not required to enter all tests in a panel. If you do not enter a result, you must type a comment. If you do enter all results, the Event Status on the Study - Events-Schedule page for the sample barcode changes to Completed.

- Click **SAVE**.
- In the Approval area, type your User ID, password, and a Comment, and click **Apply**.

If the sample has a Review status of approved or Reviewed, the status is changed to Revised.

If the sample is associated with a LabPas Recruiting screening event and the Eligibility Review status is completed, the status is changed to Pending.

If a result violates the Out of Range limits defined for a test on the Tests page, an error occurs, and you cannot save.

When a result record is saved, the source is updated to LabPas only if the change impacts any field other than Clin. Sig. or Comment that is associated with the result.

Adding a comment is not required if the Source of the result is not blank or if it is LabPas. If, however, the test is Editable and any value other than Repeat, Clin. Sig., or Comment is modified, the edit checks are re-enabled and the comment field is required.

If any entries violate edit checks, the following actions occur:

- **Warn** or **Warn and Alert** action—A warning message appears.
- **Alert** or **Warn and Alert** action—**Failed Edit Check** appears in red in the Alert field, and the test and panel names appear in red. Point to the Alert field to view the message of the edit check.
- **Prevent**—A warning message appears, and you cannot save until you correct the results that violated the edit check.

- 6 To change another panel, select the panel from the **Panel** drop-down list.

After you enter all panels, the Event Status for the sample changes to Completed.

If you save edits for a sample that had an Approval Status set to Approved, the Approval Status changes to Not Approved, and the Approval Date and Approved By fields are cleared. An entry is recorded in the CT Change Log with a source of Study Data Approval.

If you save edits for a sample that had a Monitor Review Status set to Reviewed, the Monitor Review Status changes to Not Reviewed. An entry is recorded in the CT Change Log with a source of Study Data Approval. A comment stating reviewed data has changed is saved with the audit record.

If the sample entered is associated with an SR screening event, the Eligibility Review for the volunteer associated with the sample changes to Pending provided that the Eligibility Review was set to Completed. An entry is recorded in the Recruiting Change Log with a source of Study Participant Approval. A comment stating approved data has changed is saved with the audit record.

CHAPTER 11

Removing vessels from storage

In this chapter

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Tasks: Inventory Storage page

On the Inventory Storage page, you view all vessels associated with ad hoc samples, scheduled samples, and aliquots that are stored in storage devices at your facility. You can also remove a vessel from storage.

The page displays all vessels that have been stored using either the Storage task or the Sample Storage page.

The CT Inventory History report displays the audit history for all vessels in storage.

For information about moving samples from one storage device to another, see Sample Storage page.

- ***Removing vessels from storage*** (on page 85).

Removing vessels from storage

Prerequisites:

- At least one storage device must exist.
- At least one vessel barcode must exist.

If the vessel is a group vessel then all associated vessels are also removed from storage.

- 1 From the main menu, select **Sample Management > Inventory Storage**.

The Inventory Storage page appears.

- 2 Select the boxes to the left of the vessels to remove, and click **REMOVE**.

Field descriptions for the Inventory Storage page

Field	Description	Notes
Storage Device	Device in which the vessel is stored.	READ-ONLY.
Vessel Barcode	Vessel barcode for the sample.	READ-ONLY.
Sample Id	Identifier assigned to the sample when the schedule was created.	READ-ONLY.
Study Id	Study ID and description of the study from which all samples in the task originated.	READ-ONLY.
Shelf	Shelf on which the vessel is stored.	READ-ONLY.
Rack Id	Rack on which the vessel is stored.	READ-ONLY. A value appears only if the storage device includes racks.
Rack Position	Position of the rack on which the vessel is stored.	READ-ONLY. A value appears only if the storage device includes racks.
Box Id	Identifier of the box in which the vessel is stored.	READ-ONLY. A value appears only if the storage device includes boxes.
Box Position	Position of the box in which the vessel is stored.	READ-ONLY. A value appears only if the storage device includes boxes.
Active Vessel	Yes or No, indicating whether the vessel is active.	READ-ONLY.
Vessel Type	Type of the vessel.	READ-ONLY.
Storage Date	Date in which the vessel was placed in storage.	READ-ONLY.

Field	Description	Notes
Stored By	Person who placed the vessel in storage.	READ-ONLY.

A confirmation dialog box appears.

- 3 Click **OK**.

You return to the Inventory Storage page. The vessels are removed from the inventory storage list.

CHAPTER 12

Linking a sample handled by an external lab

In this chapter

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Tasks: Sample Transfer page

On the Sample Transfer page, you can link the barcode for a sample that has been logged with the LabPas application (an internal sample) with the barcode for an outside clinical lab. This process is critical for tracking a sample that is handled by an outside lab.

You can complete the transfer process either before the sample is shipped to an outside lab (if the sample originates with your facility) or when you receive the sample from the outside lab (if the sample was initially collected by another lab).

- *Transferring a sample* (on page 89).

Transferring a sample

Prerequisite: If the **Sample Logging Required** field is selected during configuration of LabPas CT module, the sample must be logged before it can be transferred. Otherwise, logging is not required.

- 1 From the main menu, select **Sample Management > Sample Transfer**.

The Sample Transfer page appears.

- 2 Scan or type the barcode for the sample.
- 3 Fill in the other fields on the page, and click **SAVE**.

Field descriptions for the Sample Transfer page

Field	Description	Notes
Sample Barcode	Barcode of a clinical sample.	<p>The sample must be associated with:</p> <ul style="list-style-type: none"> • An active study and group for the current facility. • An active study, if the Sample Barcode is associated with a LabPas Recruiting module screening sample. • An active study, group, and period if the Sample Barcode is associated with a LabPas CT module screening sample. <p>The sample must have a status of In Progress.</p>
External Order Id	The barcode that identifies the external lab.	This id cannot be used by another sample associated with the same subject or candidate in this study.
Comment	A comment about the transfer, sample, or other issue.	

- 4 Click **SAVE**.

After you enter a valid barcode, the read-only fields in the middle of the page are filled with data associated with the sample.

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