

DCTD Standard Operation Procedure (SOP)

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Doc. #:	LHTP003.08.03	Revision:	02	Effective Date: 12/12/2012

Pharmacodynamic Assay Development and Implementation Section (PADIS)

Applied Developmental Directorate

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Frederick National Laboratory for Cancer Research

Technical Reviewer: Lihua Wang Date: 12/12/2012

QA Review: Yvonne A. Evrard Date: 12/12/2012

PADIS Approval: Robert J. Kinders Date: 12/12/2012

Change History

Revision	Approval Date	Description	Originator	Approval
00	6/1/2011	New Document	LW	RJK
01	6/15/2011	Section 6.2 allows for Thursday shipments with prior approval.	LW	RJK
02	12/12/2012	Update contact information for specimens	LW, TP	RJK

Please check for revision status of the SOP at

<http://dctd.cancer.gov/ResearchResources/ResearchResources-biomarkers.htm>

and be sure to use the current version.



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1.0 PURPOSE

The purpose of this SOP is to describe the procedures for collection, preparation, and shipment of human blood specimens from Clinical Centers.

2.0 SCOPE

This SOP applies to all Clinical Center personnel responsible for collecting, preparing and shipping blood specimens from patients participating in clinical trials.

3.0 HEALTH & SAFETY

Handle all biological specimens and blood collection sharps according to the policies and procedures of the company. Use personal protective equipment to protect against blood spills and leaks and bloodborne pathogens.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of the Clinical Site Coordinator to assure compliance with this procedure.

4.2 It is the responsibility of the Research Technician to execute this procedure.

5.0 MATERIALS AND EQUIPMENT REQUIRED

5.1 CellSave® Preservative Tubes, 10.0 mL capacity (Veridex, Cat#: 7900005)

5.2 ApoCell specimen collection kit:

- Styrofoam box
- Shipping cardboard box
- CRT packs
- Package labels

5.3 Blood shipping tube holder or a 50-mL Falcon centrifuge tube

5.4 Patient specimen labels

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6.0 OPERATING PROCEDURES

6.1 Collection of specimens into CellSave Preservative Tubes

- 6.1.1** Prepare labels for each specimen to be collected.
- 6.1.2** Draw the initial sample prior to initiation of a therapy regimen. Subsequent samples can be drawn after the start of a therapy regimen, usually at 3- to 4-wk intervals, to follow CTC levels during therapy.
- If the patient is on doxorubicin therapy, allow at least 7 d following administration of a dose of doxorubicin before blood draw.
- 6.1.3** Collect the whole blood aseptically by venipuncture or from a venous port into a CellSave Preservative Tube only.
- 6.1.4** Fill a minimum of **8-mL volume for a 10-mL capacity tube** until the blood flow stops to ensure the correct ratio of sample to anticoagulant and preservative.
- 6.1.5** Immediately mix the specimen tube by gently **inverting** the tube 8 times; tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results.
- 6.1.6** Specimens must be processed within 96 h of collection.
- 6.1.7** Blood specimens may be stored or transported in CellSave Preservative Tubes for up to 96 h at room temperature (15°C to 30°C) prior to processing. Do not refrigerate or freeze specimens.
- 6.1.8** Label each tube with specimen ID and type, time point – cycle and day number, sample date / time and operator’s initials.
- 6.1.9** **Specimens must be shipped within 24 h of collection** to ensure quality results, and PADIS is to be notified by e-mail on the day of shipment.
- 6.1.10** Complete the appropriate section of the **Specimen Submission Form** (Appendix 1) for each shipment.

6.2 Packaging Instructions

Important:

DO NOT SHIP on a Friday or Saturday.

Thursday shipments require prior approval and must be shipped using “Overnight Early AM Delivery.” Contact Dr. Lihua Wang directly by phone (do not leave a message) or e-mail with confirm receipt. Contact information in SOP Step 6.3.1***

- 6.2.1** Store CRT packs at room temperature (15°C - 30°C). **DO NOT** refrigerate or freeze CRT packs.

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6.2.2 Place a room temperature CRT pack in the bottom of a Styrofoam shipping container.



6.2.3 Wrap absorbent paper around the specimen filled CellSave Preservative tube and place in a 50-mL Falcon centrifuge tube or blood shipping tube.



6.2.4 Place the tube in the Styrofoam box on top of the CRT pack.



6.2.5 Put a second room temperature CRT pack on top of the tube.



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- 6.2.6** Insert the completed **Specimen Submission Form** in the box on top of the CRT gel pack.



- 6.2.7** Close the Styrofoam box and place in a cardboard shipping box.



- 6.2.8** Seal and adhere the return shipping labels to the outside of the box.

- 6.2.9** Notify SAIC-Frederick contact person of the shipment by e-mail.

6.3 Shipping Instructions

Important: Specimens **must** be shipped on day of collection

- 6.3.1** Contact information:

Lihua Wang

301-846-6870

wanglih@mail.nih.gov

Kathleen Tokar

301-624-8768

tokarkf@mail.nih.gov

- 6.3.2** Please send an e-mail on the day of shipment to both Lihua Wang (wanglih@mail.nih.gov) and Kathleen Tokar (tokarkf@mail.nih.gov).

- 6.3.3** Ship specimens to:

Dr. Lihua Wang
 PADIS, LHTP
 C/O Kathleen Tokar
 SAIC-Frederick, Inc., FNLCR
 8490 Progress Drive, Suite 400
 Frederick, MD 21701
 Tel: 301-624-8768

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APPENDIX 1: SPECIMEN SUBMISSION FORM

If submitting more than 15 specimens, attach an additional Specimen Submission Form.

NOTE: Record times using **military time** (24-h designation); e.g., specify 16:15 to indicate 4:15 PM

<i>Complete the information below and submit with specimens:</i>						
Protocol No./CTEP No.:						
Total No. Specimens:				Shipment Date:		
Item No.	Specimen ID / Specimen Type	Date of Collection	Time of Collection	Cycle#	Day#	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Specimen(s) prepared by: _____

Date: _____