

 (Web Link)	National Biobank Consortium of Taiwan Standard Operating Procedure	No.: NBCT SOP-012
	Title: NBCT Specimen Dispensing Process (2):Room Temperature Transport	Version/Total Pages: No. 1.1 / 9 pages
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1. Purpose

“National Biobank Consortium of Taiwan” (hereinafter referred to as the “Integration Platform”) primarily integrates domestic human biobanks and their biospecimens and data through a cloud-based system, and makes them available for application and use by medical, clinical, industry, and related biomedical research investigators nationwide. To achieve cross-institutional collaboration, maintain good quality of specimens and their data, and ensure consistency in the steps for dispensing specimens and their data, so as to facilitate future related research, this Standard Operating Procedure is hereby established.

2. Scope of Application

This dispensing SOP applies to all Integration Platform biobank specimen dispensing that follows a room-temperature transport process for blank section specimens.

3. Responsibilities

All human biobanks that have joined the Integration Platform, when dispensing blank section specimens via room-temperature transport, are recommended to follow this Standard Operating Procedure.

4. Description

This SOP can be divided into three stages

1. Blank Section Specimen Dispensing to Integration Platform Central Laboratory Process
2. Blank Section Specimen and Data Receipt Confirmation Process
3. Applicant Pickup of Blank Section Specimen and Data at Integration Platform Central Laboratory Process

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5. Operating Procedures

5.1 Blank Section Specimen Dispensing to Integration Platform Central Laboratory Process

Consumables:

1. Blank section specimen slide box (a different number of slide boxes may be selected depending on the number of slides)
2. Borderless white labels (A4 multi-purpose computer labels, 17x25mm², 112 labels per sheet)
3. Fragile-item labels

Procedure:

1. The Central Office shall, based on the order in which each Platform Biobank returns its approval letter, assign sequential numbers to the specimens for the application; the Platform Biobank that replies first shall be listed first. The numbering convention is NB-[application number]-[specimen sequence number].
2. The Central Office shall notify the Platform Biobank related to each application of the sequential number, number of cases, and specimen type.
3. Once the applicant has completed payment, the Central Office shall notify the Platform Biobank related to the application to dispense the specimens and data. The Integration Platform office shall provide the coding for each application's specimens and biological data, using sequential numbering.
4. Each Platform Biobank shall use a printer to print the Integration Platform case code onto the blank section label.
5. Blank paraffin section specimens, once completed, shall first be placed in a 42°C oven and baked for at least two days, to remove moisture.
6. Affix the printed Integration Platform case code blank section label onto the white frosted surface of the blank paraffin section slide, and place them in numerical order into the slide box.

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7. Place several neatly folded sheets of A4 paper on top of the slides, close the slide box lid, and gently shake the slide box, listening for the sound of slides shifting. If a shifting sound is heard, repeat the process of adding A4 paper and listening, until no shifting sound is confirmed.
8. Blank paraffin section specimens, once prepared and ready for dispensing, must have a specimen list dedicated to blank paraffin sections created according to the format established by the Central Office.
9. Add a layer of bubble wrap around the outside of the slide box, and secure it with wide tape. Place the impact-protected slide box, in numerical order by slide box number, into a cardboard box, and place the specimen shipping list for this shipment into an envelope or resealable bag before sealing the box.
10. and the packed cardboard box to the courier, using the NHRI's cash-on-delivery courier form, addressed to No. 35, Keyan Road, Zhunan Township, Miaoli County, NHRIR1-B1111, "National Biobank Consortium of Taiwan Central Laboratory," telephone: 037-206166, ext. 33334,33335 Ship via "room-temperature courier," which shall arrive within 24 hours. (Note: On the courier form, be sure to indicate: 1. Item: research slides; 2. Select room-temperature transport; 3. Check the box for delivery before noon; 4. Circle "fragile item" and affix a fragile-item label.)
11. Send the electronic file of the specimen list for this shipment to the National Biobank Consortium of Taiwan Central Laboratory's specimen-receiving assistant (070925@nhri.edu.tw), with a copy to the Integration Platform Chief Executive (sfhuang@nhri.edu.tw). All laboratory correspondence must be copied to the Integration Platform Chief

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Executive.

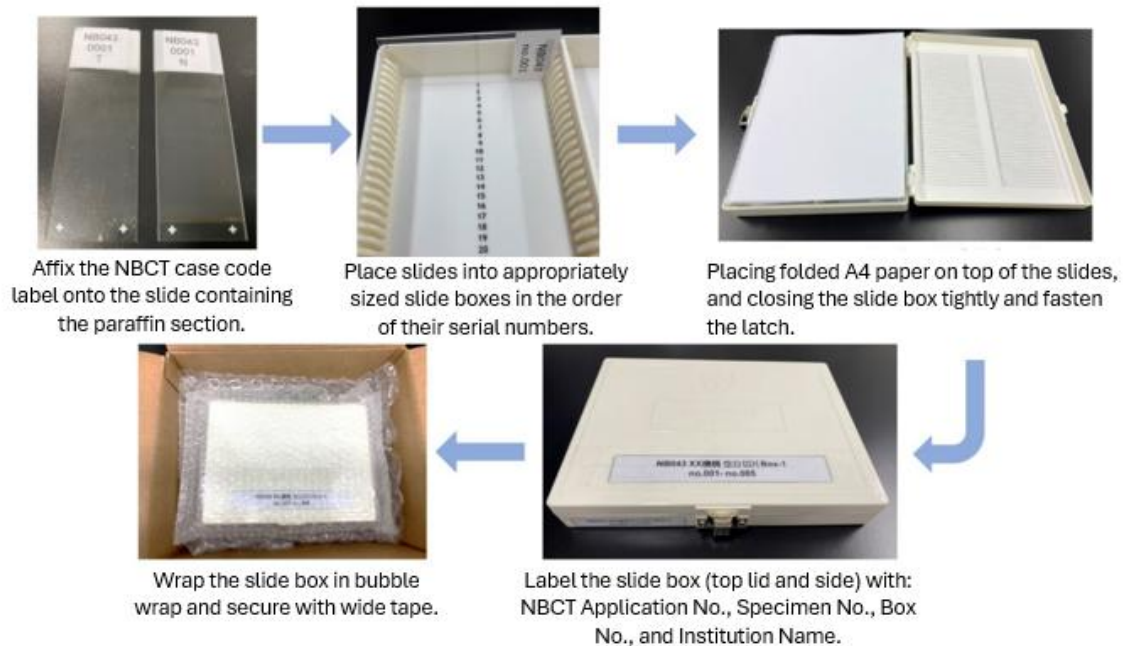
12. After the specimens have been shipped, the Platform Biobank's information staff shall encrypt the de-identified and coded basic clinical data file, burn it to a disc, and send it by registered mail to the Integration Platform Central Office's information core staff. (Attachment 2: Example of Basic Clinical Data Field). Information core telephone: 037-206166, ext. 33332, 33337.

Precautions:

1. All blank paraffin sections must use coating slides.
2. Blank section labels: please purchase borderless white labels (A4 multi-purpose computer labels, 17x25mm, 112 labels per sheet) from a stationery store; these may be printed with a printer.
3. The lid and side of the slide box must be marked with the Integration Platform application No., specimen number, and slide box number
4. .If dispensing can be completed within 2 weeks, blank paraffin sections may be stored at room temperature; otherwise, they should be kept in the 4°C freezer until dispensed.

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Blank Section Specimen Dispensing Process Flowchart 1:



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Blank Section Specimen Dispensing Process Flowchart 2:



Place the shock-protected slide box into the cardboard box, and include the specimen transport manifest for this shipment inside an envelope or sealable bag.



Seal the box and mark 'Fragile' on the outside, then affix a fragile warning sticker. Use the NHRI courier waybill for cash on delivery (COD), and ensure delivery within 24 hours.



(Notes: 1. Specify 'Research Slides' as the product description on the waybill, 2. Check 'Delivery before noon', 3. Circle 'Fragile', 4. Ship at room temperature.)

Blank Section Specimen List Format and Example

Quantity No.	NBCT Sequential No.	Biobank ID No.	Number of Slides (slides)	Slide Box No.
1	NB043-001T		10	box-1
2	NB043-001N		10	box-1

Note: For tumor tissue slides, a pathologist must first confirm that there is sufficient tumor tissue; however, because tumor characteristics vary, no specific percentage threshold is required.

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5.2 Blank Section Specimen and Data Receipt Confirmation Process

- Blank section specimens, when transported to the NHRI “National Biobank Consortium of Taiwan Central Laboratory,” the assistant responsible for receiving the specimens must first check whether the cardboard box is intact, to confirm that the specimens were not subjected to a severe impact during transport. The slide box shall then be opened, and the blank section specimen quantity verified for correctness, and the slides checked for any breakage; the slide box shall then be placed into the Integration Platform's dedicated 4°C freezer for storage, and the Platform Biobank notified by e-mail that the blank section specimens have been received. Blank section specimens, and this shall be recorded in the specimen receipt log. The assistant receiving the specimens, if
- they discover **that** blank section specimen quantities do not match or that slides are broken, must take photographic evidence, and immediately contact the shipping Platform Biobank's staff to clarify the issue, note it in the specimen receipt log, and report it to the Quality Team Leader and the Chief Executive. The Chief Executive shall decide on the next course of action. When the Integration Platform Central Office's information core staff receive the encrypted, de-identified, and coded basic clinical data file disc, they shall
- notify the Platform Biobank by e-mail that the data has been received, and note this in the application case's receipt log.

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5.3 Applicant Pickup of Blank Section Specimen and Data at Integration Platform Central Laboratory Process

Procedure: **Because specimens**

1. are extremely precious, and in the event of damage cannot be compensated, they cannot be shipped to the applicant, so the Integration Platform Central Laboratory assistant will ask the applicant or a member of their team to come to the NHRI Integration Platform Central Laboratory in person to collect the specimens. The Integration Platform Central Laboratory assistant shall first notify the applicant and their contact person by e-mail
2. , informing them that the blank section specimens for their application have been prepared, along with the available pickup time, location, telephone number, contact person, and other information. All correspondence must be copied to the Integration Platform Chief Executive. The Integration Platform Central Laboratory assistant shall then call the applicant or their contact person to confirm
3. , explain the precautions for collecting the specimens, and ask them to reply by e-mail informing them of the pickup time at NHRI, the name of the person picking up the specimens, and their contact telephone number. The person collecting the specimens need not be the applicant themselves. All correspondence must be copied to the Integration Platform Chief Executive. The Integration Platform Central
4. Laboratory assistant, two hours before the applicant is expected to arrive at the NHRI to collect the blank section specimens, shall remove the blank sections from the 4°C freezer and place them in
5. the 37°C oven for 2 hours, to remove moisture. Once the applicant (or their designated representative) arrives at the laboratory, the dried blank sections shall then be taken out,

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6. allowing the applicant's representative to inspect the condition and quantity of the blank section specimens one by one. Once everything has been verified correct, the blank section specimens shall then be packed
7. . Place several neatly folded sheets of A4 paper on top of the slides, close the slide box lid, and gently shake the slide box, listening for the sound of slides shifting. If a shifting sound is heard, repeat the process of adding A4 paper, shaking, and listening, until no shifting sound is confirmed. Add a layer of bubble wrap around the outside of the slide box, and secure it with wide tape. Place the impact-protected slide box, in numerical order by slide box number, into a cardboard box, or into a sturdy shopping bag brought by the applicant (or their designated representative).
8. Ask the applicant (or their designated representative) to sign the Specimen Pickup Receipt (see Attachment 1).
9. Once the blank section specimens have been picked up, the Integration Platform Central Laboratory assistant shall provide the applicant and their contact person, by e-mail, with the electronic file of the application case's blank section specimen list showing only the sequential numbers, as well as a scanned copy of the Specimen Pickup Receipt signed by the applicant (or their designated representative), with a copy to the Integration Platform Chief Executive. Once the blank section specimens have been picked up,
10. the Integration Platform Central Laboratory assistant must also notify the Integration Platform Central Office's information core staff that dispensing of specimens for the application has been completed. The
11. Integration Platform Central Office's information core staff must first verify the application case's de-identified basic clinical information files (from different

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institutions). Once assembled in the original sequential order, a second information core staff member must verify and confirm correctness, after which the basic clinical information file for the application shall be provided to the applicant by e-mail; the cases in this file must be fully de-identified, containing only sequential numbers.

12. The application's de-identified basic clinical information file, if the application's case count exceeds one thousand cases, cannot be provided directly to the applicant; the applicant must instead go to the Central Office's information core independent workspace to use it on a one-time basis, and it cannot be downloaded or removed.

Precautions:

1. If blank section specimens were already stored at room temperature, there is no need to bake them.
2. The applicant (or their designated representative)'s signed Specimen Pickup Receipt original, shall be retained by the National Biobank Consortium of Taiwan Central Laboratory, only a scanned copy of the Specimen Pickup Receipt need be given to the applicant.

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6. Attachments

Attachment 1: Example of Specimen Pickup Receipt

RECEIPT

Customer No.:

Receipt No.:

Customer Name:

Date Completed: Year Month Day

Address:

Telephone:

Fax:

Valid for: 90 days

Additional Notes:

Item

Description	Quantity	Unit	1
N	B-05Preparation of blank sections case	slides/case	Customer Signature: Date:

Prepared by:

National Biobank Consortium of Taiwan Central Laboratory / NHRI Human Biobank Laboratory

Handled by:

Telephone:

Ext.

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Attachment 2: Example of Basic Clinical Data Field

(The basic clinical data fields appropriate for each type of disease may be found in the Information Section of the Integration Platform website)

Clinical Data Fields for Oral Cancer Cases							
Sequential No.	Biobank ID No.	gender	Age	smoking history	betel nut chewing history		
CEA (ng/ml)	Hb (g/dL)	Platelet (10 ³ /uL)	Clinical stage:T	Clinical stage:N	Clinical stage:M	*Clinical stage	
Pathology Diagnosis	tumor size(cm)	tumor number	Tumor grade	Tumor site	vascular invasion	perineural invasion	Closest Tumor margin (cm)
Pathology stage:T	Pathology stage:N	Pathology stage:M	*Pathology stage	metastatic site			

*Clinical and Pathology staging according to AJCC, 8th edi.

Leave blank if there is no relevant data

Clinical Data Fields for Lung Cancer Cases						
Sequential No.	Biobank ID No.	gender	Age	smoking History	history of pulmonary tuberculosis	
Clinical stage:T	Clinical stage:N	Clinical stage:M	*Clinical stage	CEA	Hb	Platelet
Pathology Diagnosis	tumor size(cm)	Tumor site	treatment before surgery			
Pathology stage:T	Pathology stage:N	Pathology stage:M	metastatic site	*Pathology stage		
EGFR mutation	KRAS mutation	HER2 mutation	ALK mutation	other genes		
*Clinical and Pathology staging according to AJCC, 8th edi.						
Leave blank if there is no relevant data						