

## AlloMap Sample Handling

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**Purpose** This document provides instructions for AlloMap sample preparation.

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- Policy**
- All sample processing must be completed at room temperature.
  - All samples collected by MOB lab staff must be hand delivered to a CLS or MLT for timely processing.
  - Samples received by the main lab staff collected by a provider should be given to a CLS or MLT immediately upon receipt.
  - A manager or supervisor should be informed of all Allomap specimens upon completion of collection by MOB lab staff and upon receipt.
  - The CLS or MLT that begins the processing should be the same that places the specimen in the freezer and completes the documentation. A manager is notified if there are problems or issues.
  - All processed sample must be frozen within 2 hours of blood collection.
  - Problems or issues encountered during processing must be communicated to a manager. The manager will notify the Post-Transplant Coordinator.
  - Sample processing reagents must be stored at room temperature (18-25°C).
  - Use reagents supplied by XDx only.
  - Expiration date and inventory level of Allomap reagents and shipping boxes must be checked by CLS or MLT.
  - Do not mix reagents between packs.
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- Workplace Safety**
- All laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures.
- For standard precautions and safety practices in the laboratory; see LGM 8000, specifically, but not limited to, equipment safety, proper body mechanics, sharps exposure and proper use of personal protective equipment (PPE).
  - Do not mix LyseDx™ lysing reagent with chlorine bleach.
  - When cleaning LyseDx™ lysing reagent spills, clean first with soapy water and follow with chlorine bleach if necessary.
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## AlloMap Sample Handling, Continued

**Reagents/  
Supplies**

- Phosphate buffered saline (PBS)
- LyseDx™ lysing reagent
- Transfer pipet
- Aqui-Pak 6-Bay absorbent pouch
- 95 kPa Specimen Transport Bag
- Styrofoam cooler
- List of Contents Card
- Shipping Packet

**Sample**

- 8ml of blood in a BD Vacutainer® CPT™ Cell Preparation Tube with sodium citrate

**Procedure**

**AlloMap Documentation and Notification:**

Step	Action						
1	Receive the specimen from the courier and document in LSPM 244A- <i>Allomap Specimen Handling Form and Process Map</i> as indicated (#4).						
2	Notify a manager that the Allomap Specimen has been received and document on the form (#5).						
3	Evaluate the lot number and expiration date of reagents prior to processing and the inventory of shipping boxes. <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>Number of reagent vials <math>\leq</math> 5 or shipping boxes <math>\leq</math> 2</td> <td>Inform a manager to reorder supplies</td> </tr> <tr> <td>Reagent vials expire in &lt;7 days</td> <td>Inform a manager to reorder</td> </tr> </tbody> </table>	If	Then	Number of reagent vials $\leq$ 5 or shipping boxes $\leq$ 2	Inform a manager to reorder supplies	Reagent vials expire in <7 days	Inform a manager to reorder
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Number of reagent vials $\leq$ 5 or shipping boxes $\leq$ 2	Inform a manager to reorder supplies						
Reagent vials expire in <7 days	Inform a manager to reorder						
4	Initiate documentation on the <i>Allomap Specimen Log</i> .						
5	Inform a manager immediately if there are any issues with AlloMap supplies or inventory.						

**Procedure**

**Allomap Sample Preparation**

Step	Action
1	Centrifuge the specimen at 3400RPM for 15 minutes at room temperature.
2	Re-suspend the mononuclear cells into the plasma by inverting the CPT tube at least 10 times.
3	Wash the cells with phosphate buffered saline (PBS) by pouring the cell/plasma mixture into a PBS tube found in the Reagent Pack. Invert at least 10 times to mix.

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## AlloMap Sample Handling, Continued

### Procedure Allomap Sample Preparation (continued)

4	Label the PBS tube with a barcode label from the XDx test requisition form.
5	Centrifuge PBS tube at 3400RPM for 5 minutes.
6	Pour off the supernatant until only the cell pellet remains.
7	Lyse the cells in the pellet by using a transfer pipet supplied in the Pack, transfer the entire contents of one LyseDx lysing reagent vial to the cells and vigorously pipet the cells and the LyseDx lysing reagent up and down until the cells have disappeared and the lysate is clear.
8	Freeze the lysate at -15°C or colder, or in dry ice.
9	Note the “Sample in Freezer Time” on requisition.
10	Document on <i>LSPM 244B – Allomap Specimen log</i>
11	File LSPM 244A – <i>Allomap Specimen Handling Form and Process Map</i> in the designated Allomap binder.
12	Any problems or issues encountered during sample preparation and processing must be notified to a manager immediately. The manager will notify the post-transplant coordinator.

### Procedure Allomap Sample Shipping

Step	Action
1	Place the requisitions into the plastic bag and set aside.
2	Complete the List of Contents Card and set aside.
3	Evaluate the sample(s) to be shipped is/are <b>frozen</b> .
4	Place up to 6 <b>frozen</b> sample tubes into the AQUI-Pak 6-Bay absorbent pouch, and roll up pouch.  <b>Note:</b> <i>Once you begin this process, work quickly and do NOT let the samples thaw.</i>
5	Place the pouch into the 95 kPa Specimen Transport Bag, and put into the Styrofoam cooler. Up to 12 specimens (2 Aquipak 6-Bay pouches) can be shipped in one cooler.

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## AlloMap Sample Handling, Continued

**Procedure  
 Cont'd**

**AlloMap Sample Shipping**

Step	Action
6	Pack the cooler with dry ice.
7	Put the lid on the cooler. Do NOT tape shut.
8	Place the bag of requisitions and List of Contents Card on top of the lid.
9	Seal the box shut.
10	Select the appropriate Shipping Packet. Discard the other.  <b>Note:</b> <i>One packet contains an airbill and labels for shipping Monday through Thursday and the other packet contains an airbill and labels for shipping on Friday for Saturday delivery.</i>
11	Affix the completed dry ice label, shipping labels, and the appropriate shipping airbill to the outside of the box.
12	Call FedEx Express for pickup (“First Overnight” delivery Monday through Thursday, and “Saturday Hold” for Saturday delivery). If using a “Saturday Hold” sticker, ensure that the address on the sticker reads “900 Gateway Blvd, South San Francisco, CA 94080”.
12	Attach copy of airbill or tracking number to LSPM 244A - <i>Allomap Specimen Handling Form and Process Map</i> .
13	Notify manager the package is ready for shipment and document on LSPM 244A - <i>Allomap Specimen Handling Form and Process Map</i> . (#6 and #7).
14	Manager confirms the completion of packing and the shipment and documents on LSPM 244A - <i>Allomap Specimen Handling Form and Process Map</i> . (#8)

**Uncontrolled Documents**

The table below lists the uncontrolled documents

Document Number	Document Name
NA	XDx AlloMap Sample Preparation and Shipping Instruction Cards.
NA	CareDx AlloMap Test Requisition Form

**Controlled Document(s):**

The table below lists the controlled document(s) for this policy.

Document Number	Document Name
LGM 8000	Safety Practices
LSPM 240	Direct Shipping Requirements
LSPM 244A	Allomap Specimen Handling Form and Process Map
LSPM 244B	Allomap Specimen Log

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## AlloMap Sample Handling, Continued

**Author**            Marian Azuma, CLS

Reviewed and approved by:

<b>SIGNATURE</b>	<b>DATE</b>
<b>Julie Toti, CLS, MS Manager, Clinical Laboratory – Los Angeles Medical Center</b>	
<b>Hedyeh Shafi, M.D. Director, Clinical Laboratory – Los Angeles Medical Center</b>	

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## AlloMap Sample Handling, Continued

### HISTORY PAGE

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Laboratory Director review/date	Laboratory Manager review/date	Date change implemented
New					

# ALLOMAP SPECIMEN HANDLING FORM

(One form for each patient)

## To be initiated and completed by...

**MOB Laboratory** staff if collected at the MOB (i.e. 4900 Sunset) or

**4867 Laboratory** staff if collected by RN and delivered by RN or courier

**Manager must be informed of all Allomap specimens.**

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

MRN: \_\_\_\_\_

1) Specimen Collected By (NUID): \_\_\_\_\_ Time: \_\_\_\_\_

2) Manager informed of Allomap Specimen

4900 MOB Supervisor Notification to 4867 Manager/Supervisor: \_\_\_\_\_ Time: \_\_\_\_\_

3) Specimen hand-delivered to CLS by MOB/Main lab staff (NUID) \_\_\_\_\_ Time: \_\_\_\_\_

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## To Be Completed by Staff at 4867 Laboratory:

4) Specimen received & processed\* by CLS/MLT (NUID): \_\_\_\_\_ Time: \_\_\_\_\_

\*Specimen aliquot must be frozen

5) Manager/Supervisor notified by CLS/MLT: \_\_\_\_\_ Time: \_\_\_\_\_

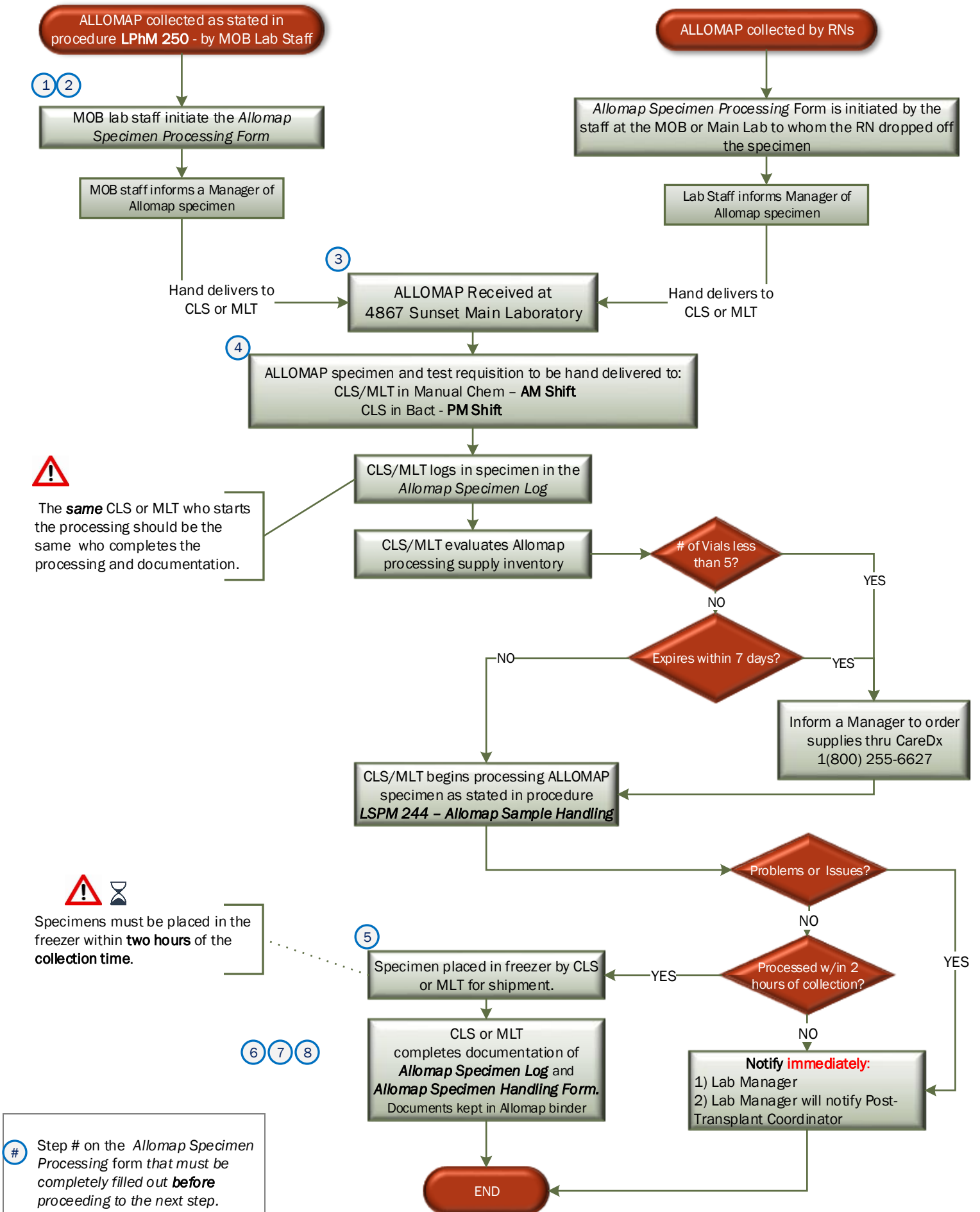
6) Specimen Prepared for shipment by Lab Asst. (NUID): \_\_\_\_\_ Time: \_\_\_\_\_

7) Manager notified by Lab Asst. of package readiness : \_\_\_\_\_ Time: \_\_\_\_\_

8) Manager/Supervisor Confirmed packaging & shipping: \_\_\_\_\_ Time: \_\_\_\_\_

\*Manager to keep this form in the Allomap binder for future reference

# ALLOMAP SPECIMEN HANDLING FORM AND PROCESS MAP



The **same** CLS or MLT who starts the processing should be the same who completes the processing and documentation.

Specimens must be placed in the freezer within **two hours** of the collection time.

**#** Step # on the *Allomap Specimen Processing* form that must be completely filled out **before** proceeding to the next step.