Standard Operating Procedure			Doc no: Onc–80304g		Page 1 of 5
SOP TITLE:	BLOOD COLLECTION, PROCESSING AND SHIPPING FOR EARLYCDT USE				Version: 1
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Purpose and overview

The purpose of this SOP is to describe the procedure for blood sample collection, processing, storage and shipping by external groups (distributors) when requesting the EarlyCDT-Lung Kit or partner studies.

Responsibilities and training requirements

Venepuncture must only be conducted by appropriately trained and qualified personnel as determined by the external group.

Risk management and health and safety

All samples must be considered as potentially hazardous and appropriate safety precautions for dealing with infective biospecimens must be taken.

All personnel are responsible for ensuring that safe working procedures are adhered to, that their clinic and laboratory facility is adequately prepared prior to starting the procedure and that all equipment required is ready to use.

Definitions

- Venepuncture is the procedure of entering a vein with a needle, usually to obtain a sample of blood.
- SOP is Standard Operating Procedure

Materials required

Forms

- N/A

Reagents

- N/A

Consumables

- Sharp Safe Bins
- Nitrile / category three (III) gloves
- Kidney Dish
- First Aid Box
- Saline Eye Wash Solution
- 21-guage needle / butterfly cannula
- Tourniquet
- Blood collection tube
- Tube rack
- Gauze / cotton wool
- Sterile adhesive dressings

- Sterile wipe
- Frozen cold packs
- Dry ice
- Shipping container
- UN3373 biological substance label
- UN1845 dry ice label

Equipment required

- Centrifuge capable of 1000xg
- Fridge (+2°C to +8°C)
- Freezer (-25°C to -15°C)
- ULT freezer (-85°C to -65°C)

Procedure:

1. Venepuncture protocol

1.1. Prior to receiving each patient, ensure that fresh gloves and sharps bin are available.

1.2. Welcome the patient.

1.3. Seat comfortably and explain the procedure.

1.4. Verify the patient's identity by checking name and date of birth.

1.5. Inspect both arms, if necessary, taking advice from the patient on which arm is best for acquiring blood samples.

1.6. Ensure that the arm is supported.

1.7. Wash hands and put on gloves.

1.8. Assemble needle as recommended by the manufacturer.

1.9. Apply tourniquet, the tourniquet is normally applied just proximal to the site of venepuncture.

1.10. Palpate antecubital area carefully at most likely site of a vein.

1.11. Clean the area with a sterile sanitising wipe and allow to dry.

1.12. Remove protective sheath from the needle and puncture the vein with the bevel of the needle in an upward position and with the shaft of the needle at an angle of thirty degrees (30º) to the skin.

1.13. Release the tourniquet and push the appropriate collection tube gently into the hub. The sample tube will then fill with blood. One tube should be collected. If vacuum is lost from the sample tube no blood will be obtained.

1.13.1. Multiple samples may be taken by inserting a fresh sample tube to the hub.

1.13.2. The following collection tubes are suitable for use with EarlyCDT products:

a) Serum - either clot activator or gel tubes.

b) Plasma - EDTA tube.

Important Note: *Plasma collected in heparin and citrate tubes* ***should not be used****.*

1.14. If the tourniquet has not already been released it should be released once the sample has been obtained.

1.15. Withdraw the needle, place it into a Sharp Safe bin and press a piece of gauze/cotton wool against the puncture site to stem the blood flow.

1.16. Apply firm pressure to the gauze/cotton wool for at least three (3) minutes or until bleeding has ceased.

1.17. Discard all contaminated waste into the appropriate waste container.

1.18. Place a sterile adhesive dressing over puncture site, if required.

2. Specimen processing

2.1. Mix or store the collection tube after blood collection as per the manufacturer's instructions.

2.2. Whole blood specimens should be stored at room temperature (+18 to +25°C) and be processed within four (4) days.

2.3. Centrifuge the clotted tubes at 1000g for fifteen (15) minutes, ensuring that the centrifuge is balanced.

2.4. Transfer the collection tubes from the centrifuge to a Biological Safety Cabinet (class is dependent upon local biosafety risk assessment) and prepare the safety cabinet for sample aliquoting. The following equipment should be available for use inside the safety cabinet:

2.4.1. Empty Sharp Safe bin(s).

2.4.2. 1.5ml pastettes / disposable pipettes.

2.4.3. Specimen pour off tubes x two (2).

2.5. Using a pastette or disposable pipette, divide the serum or plasma equally between the two (2) specimen pour off tubes. Cap each tube securely and label appropriately.

2.6. Dispose of spent blood tubes, pastettes and disposable pipettes in the sharp safe bin in the biological safety cabinet.

3. Sample storage

3.1. Oncimmune has validated the following storage times and temperatures for samples in pour off tubes:

3.1.1. +2 °C to +8°C for up to fourteen (14) days.

3.1.2. -25°C to -15°C for up to twelve (12) months.

3.1.3. -85°C to -65°C for up to twelve (12) months.

3.2. Specimens must not undergo more than five (5) freeze thaw cycles.

3.3. Bring frozen specimens to room temperature and mix thoroughly by gentle inversion before analysis.

4. Sample shipping

4.1. At time of shipping to Oncimmune, one of the duplicate pour off tubes for each patient sample should be retained frozen at -25°C to -15°C or -85°C to -65°C (in case of loss or damage of the shipped sample).

4.2. Place all samples to be sent in a suitable sample box and place along with a pad of absorbent paper into a plastic bag.

4.3. Package samples in a polystyrene shipping container with either:

4.3.1. Frozen (-20°C) cold packs.

4.3.2. Dry Ice.

4.4. Fill out the shipping manifest with details of the samples being sent.

4.5. Fix the sender and recipients details to the parcel (name, company, address and phone number).

4.6. Attach a UN3373 biological substance label to the parcel.

4.6.1. If using dry ice also attach a UN1845 dry ice label indicating the weight of dry ice.

4.7. Email the shipping manifest and the courier tracking number to recipient so that the parcel can be tracked.

4.8. Contact recipient if there is a reasonable likelihood that the sample contains a pathogen.

Quality record requirements

N/A

Revision history:

Date	Initial	Change
18.06.20	CW	New SOP ,combines Onc-80229g, Onc-80230g, Onc-80244g and Onc-80262g

References:

SOPs:

- N/A

Other:

- N/A

Appendices:

N/A