

CHANCE STUDY DOSSIER FOR THE INVESTIGATOR

SAMPLE MANAGING
& APPENDIX 1: BIOBANK SOPS
VERSION 6: February 2022

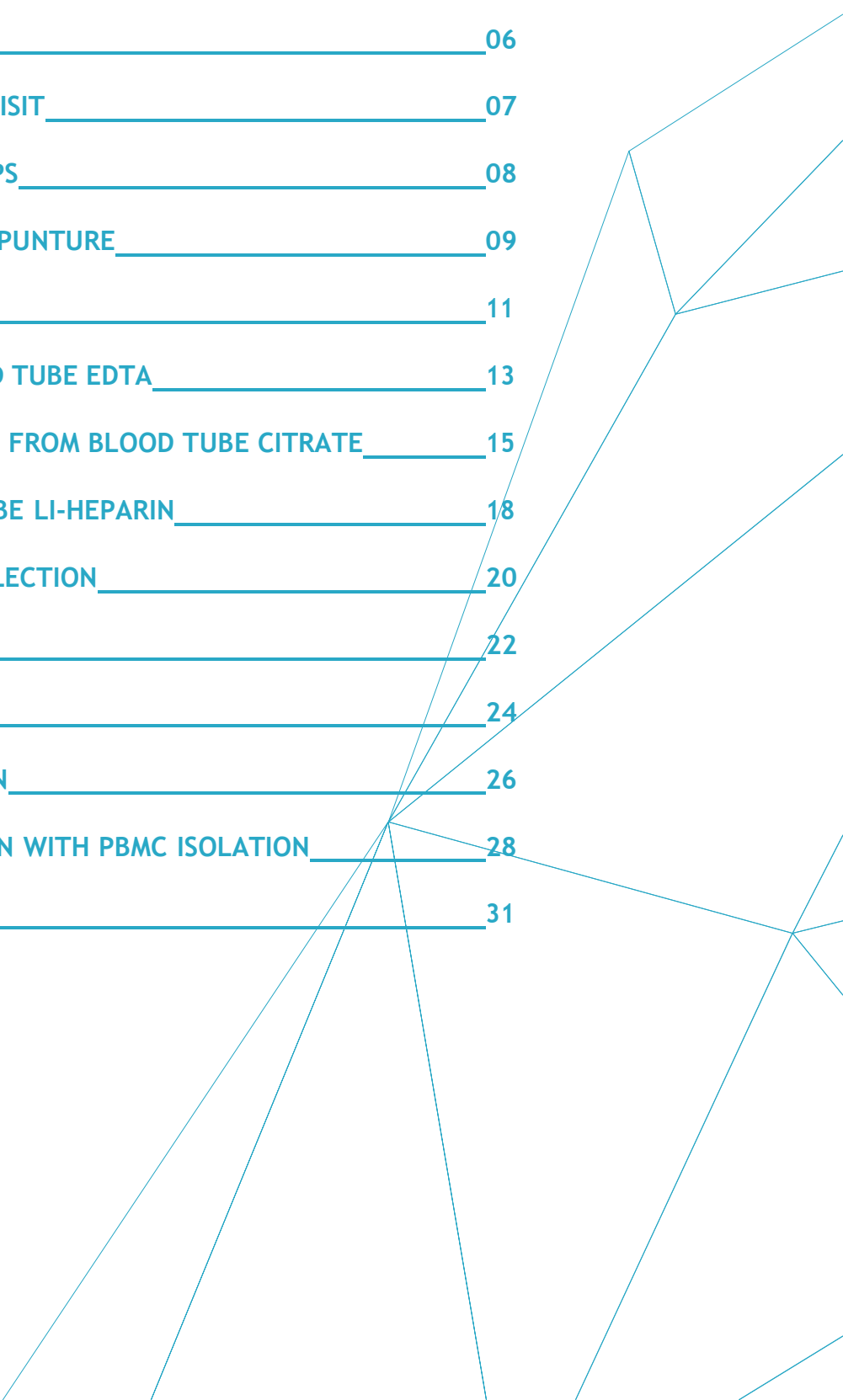


EF Clif

EUROPEAN
FOUNDATION
FOR THE STUDY
OF CHRONIC
LIVER FAILURE

Contents

SAMPLE MANAGING	03
LOGISTICS	04
MATERIAL SUPPLIED	05
SAMPLE COLLECTION	06
SAMPLES OBTAINED PER VISIT	07
APPENDIX 1: BIOBANK SOPS	08
BLOOD COLLECTION VENIPUNCTURE	09
SST TUBE SERUM	11
BUFFY COAT FROM BLOOD TUBE EDTA	13
BUFFY COAT AND PLASMA FROM BLOOD TUBE CITRATE	15
PLASMA FROM BLOOD TUBE LI-HEPARIN	18
TEMPUS BLOOD RNA COLLECTION	20
URINE COLLECTION	22
SALIVA COLLECTION	24
LIVER BIOPSY COLLECTION	26
EDTA PLASMA COLLECTION WITH PBMC ISOLATION	28
SAMPLE LABELLING	31

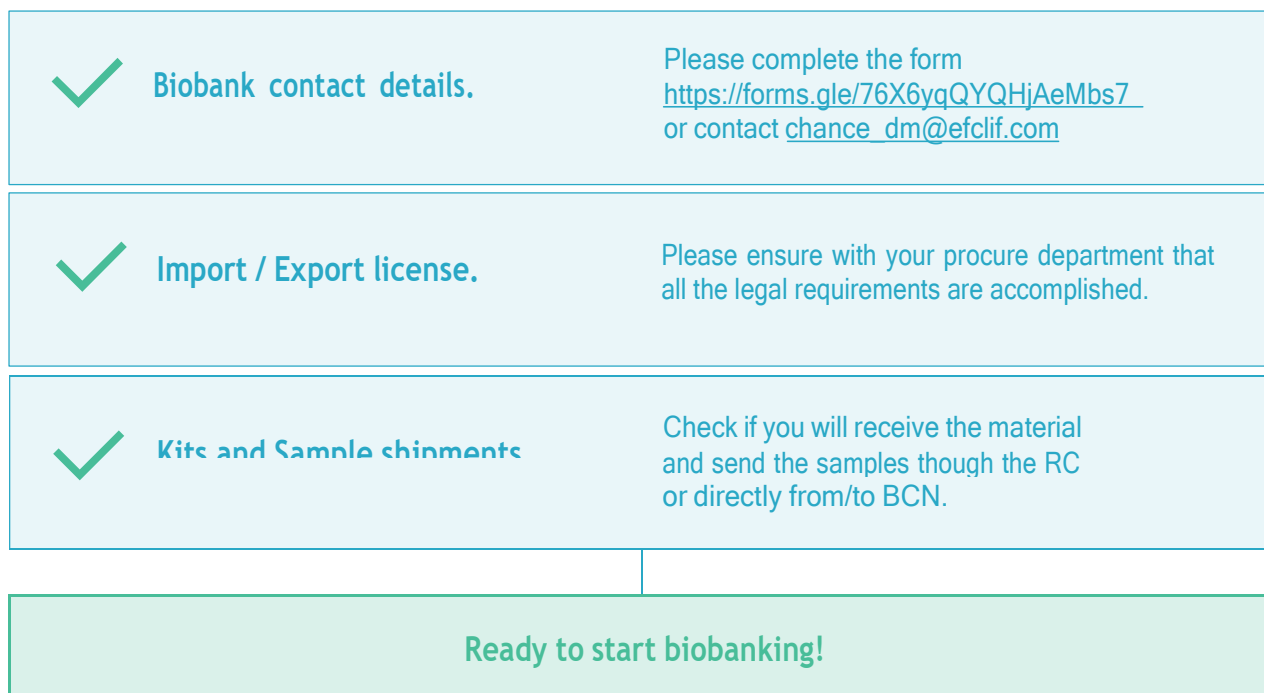


SAMPLE MANAGING

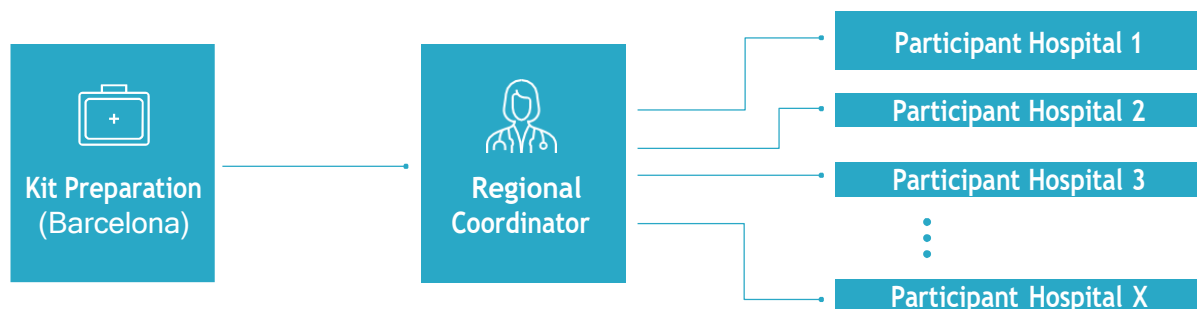


SAMPLE MANAGING

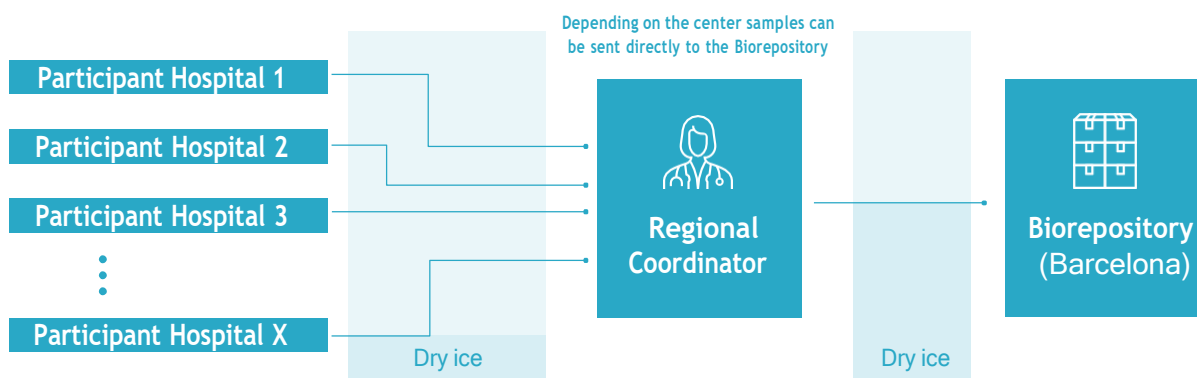
Logistics:



Material supply (at the beginning of the study):



Sample Shipment (at the end of the study):



MATERIAL SUPPLIED

 <p>SST Tubes</p>	 <p>EDTA Tubes</p>	 <p>Citrate Tubes</p>	 <p>Li-Heparin Tubes</p>
 <p>Tempus Tubes</p>	 <p>Urine Cups</p>	 <p>Falcon 15 ml.</p>	 <p>Cryotubes</p>
 <p>Wilmut seal color caps</p>	 <p>Biobanks labels</p>	 <p>1 plate 96 well PCR</p>	 <p>Pre-filled Leucosep Tubes</p>
 <p>Cryobox</p>	 <p>Racks</p>	 <p>Wilmut plates</p>	 <p>Plastic bags</p>

With each shipment you will receive a check list with the material supplied.

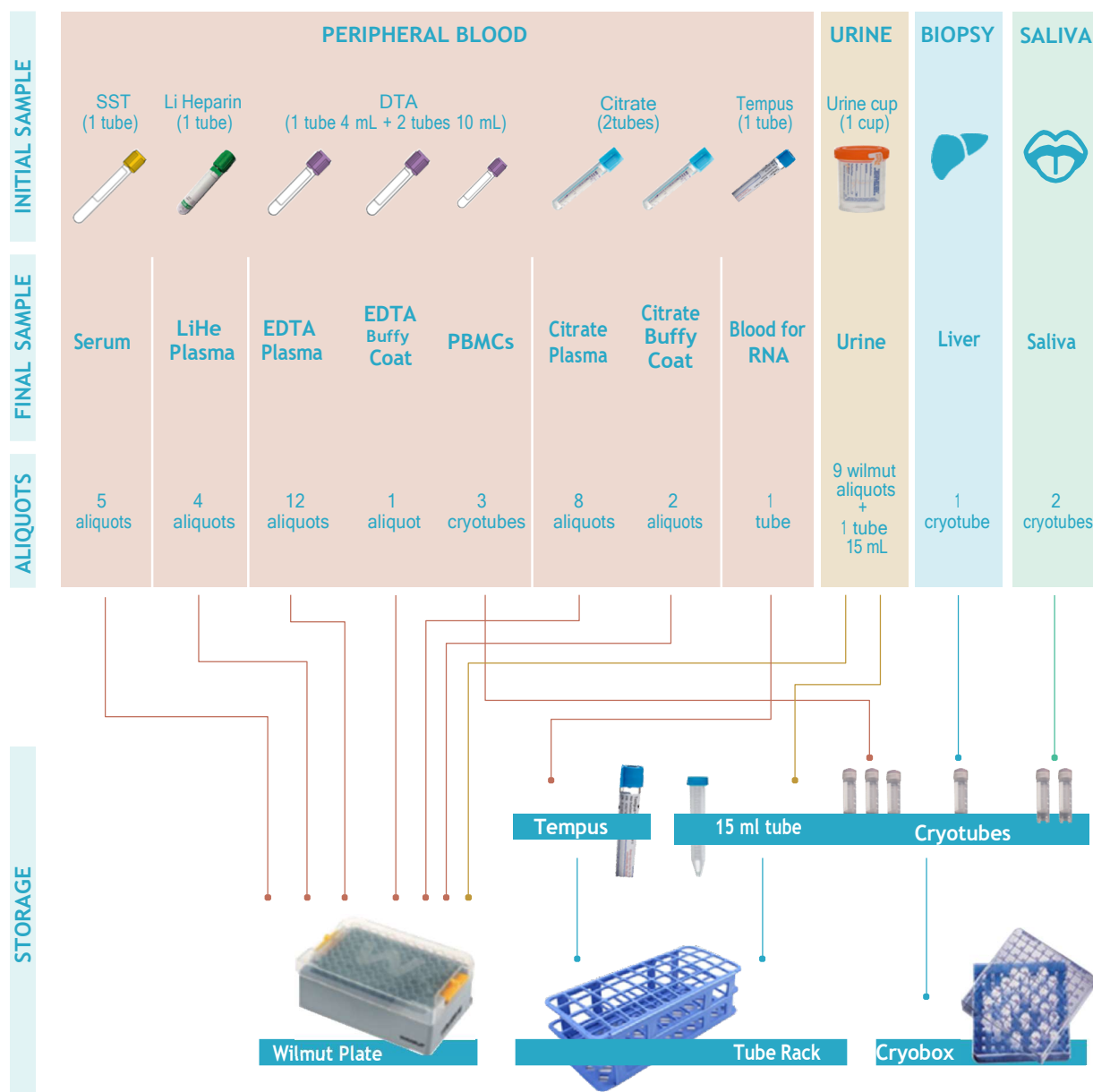
Once the content is checked, it should be signed and returned via email to chance_dm@efclif.com.

Expire dates should be checked regularly. It's strongly recommended to maintain and ordered, and updated inventory of the material received. In case of need new material send an email to chance_dm@efclif.com with enough time to not run out of stock.

SAMPLE COLLECTION

	Serum	EDTA Plasma	EDTA BC	Citrate Plasma	Citrate BC	LiHe Plasma	Urine	Tempus Tube	Saliva	PBMCs*	Liver Biopsy
PRE - LIVER TRANSPLANTATION VISITS	Inclusion visit	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Day 7 visit	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Month 3 (only patients from group 3)	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Extra visit (if applicable)	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Liver transplantation visit (before surgery)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
POST - LIVER TRANSPLANTATION VISITS	Day 3 visit post LTX	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Day 7 visit post LTX	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Day 28 visit post LTX	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Month 3 visit post LTX	✓	✓	✓	✓	✓	✓	✓	✓	✓	

SAMPLES OBTAINED PER VISIT



Samples obtained should be also ordered and inventoried immediately. After sample collection, label codes should be registered in the eCRF biobank form in order to ensure traceability.

Keep the templates for racks and cryoboxes updated and send them to chance_dm@efclif.com when completed. They should also be sent with the samples at the end of the study.

Samples must be kept at -80°C during the storage and shipment. Please contact with chance_dm@efclif.com in case of any accident, lack of space or any other relevant issue.

It is planned to send all the samples by the end of the study.

APPENDIX 1: BIOBANK SOPS





BLOOD COLLECTION VENIPUNCTURE

1. PURPOSE

This SOP describes the basic guidelines to collect blood samples by venipuncture using standard vacuum collection systems.

2. MATERIAL

Standard vacuum collection system, safety materials.

Vacuum tubes for blood collection:

- x1 SST tube (yellow cap, #367955, BD)
- x3 EDTA tubes (purple cap, #368861, BD)
- x2 Citrate tubes (blue cap, #363079, BD)
- x1 Li-heparin tube (green cap, 368884, BD)
- x1 Tempus tube for RNA (blue cap, #4342792, Thermo Fisher)

3. PROCEDURE

1.

Extend the patient's arm and inspect the antecubital fossa. Select the venipuncture site and apply the tourniquet at 3-4 inches above the selected puncture site.

2.

Cleanse the venipuncture site with 70° alcohol. Allow the area to dry.

3.

Anchor the vein by holding the patient's arm and placing a thumb **BELOW** the venipuncture site.

4.

Enter the vein swiftly at a 30 degree angle or less, and continue to introduce the needle along the vein at the easiest angle of entry.

5.

Insert the first vacutainer tube into the vacutainer holder.

6.

After blood starts to flow, release the tourniquet.

7.

Mix by gently inversion the **SST, Citrate, EDTA and Li-heparin** tubes (5 times).

Mix the **Tempus tube** vigorously (20 seconds of vigorous shaking)

8.

When finished, place a gauze pad over the puncture site and quickly remove the needle. Immediately apply pressure. Ask the patient to apply pressure to the gauze for at least 2 min. When bleeding stops, apply a fresh bandage, gauze or tape.

SST TUBE SERUM

1. PURPOSE

The SST tube or BD Vacutainer® Plus plastic serum tube (Figure 1) is an evacuated blood collection tube system containing a clot activation solution and a gel for serum separation.

This SOP describes the basic guidelines to use these tubes to collect serum samples from whole blood.

2. MATERIAL

- Routine venipuncture material.
- 1 BD Vacutainer® Plus plastic serum tube (#367986, BD) (Figure 1). Store tubes upright at room temperature and protect them from direct light.
- Centrifuge with swing-out head.
- Pasteur pipette (not provided by the EFCLIF) (Figure 2).



Figure 1



Figure 2

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided (SOP-0).

2.

Collect 5 ml of blood directly into the SST Tube (1 SST tube/patient/-visit).

3.

Gently invert 5 times to mix clot activator with blood.

4.

Allow blood to clot for a minimum of 30 min in a vertical position.

5.

Centrifuge at 1500 RCF (g) for 10 min at 4°C in a horizontal rotor (swing-out head), (remember to use the appropriate balance tube).

6.

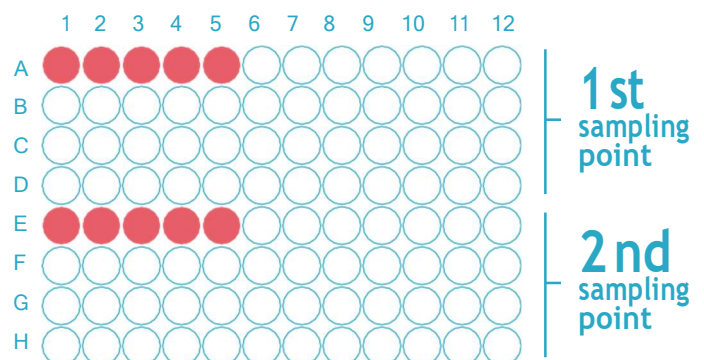
After centrifugation, barrier will form, separating serum specimen from clot (Figure 3).

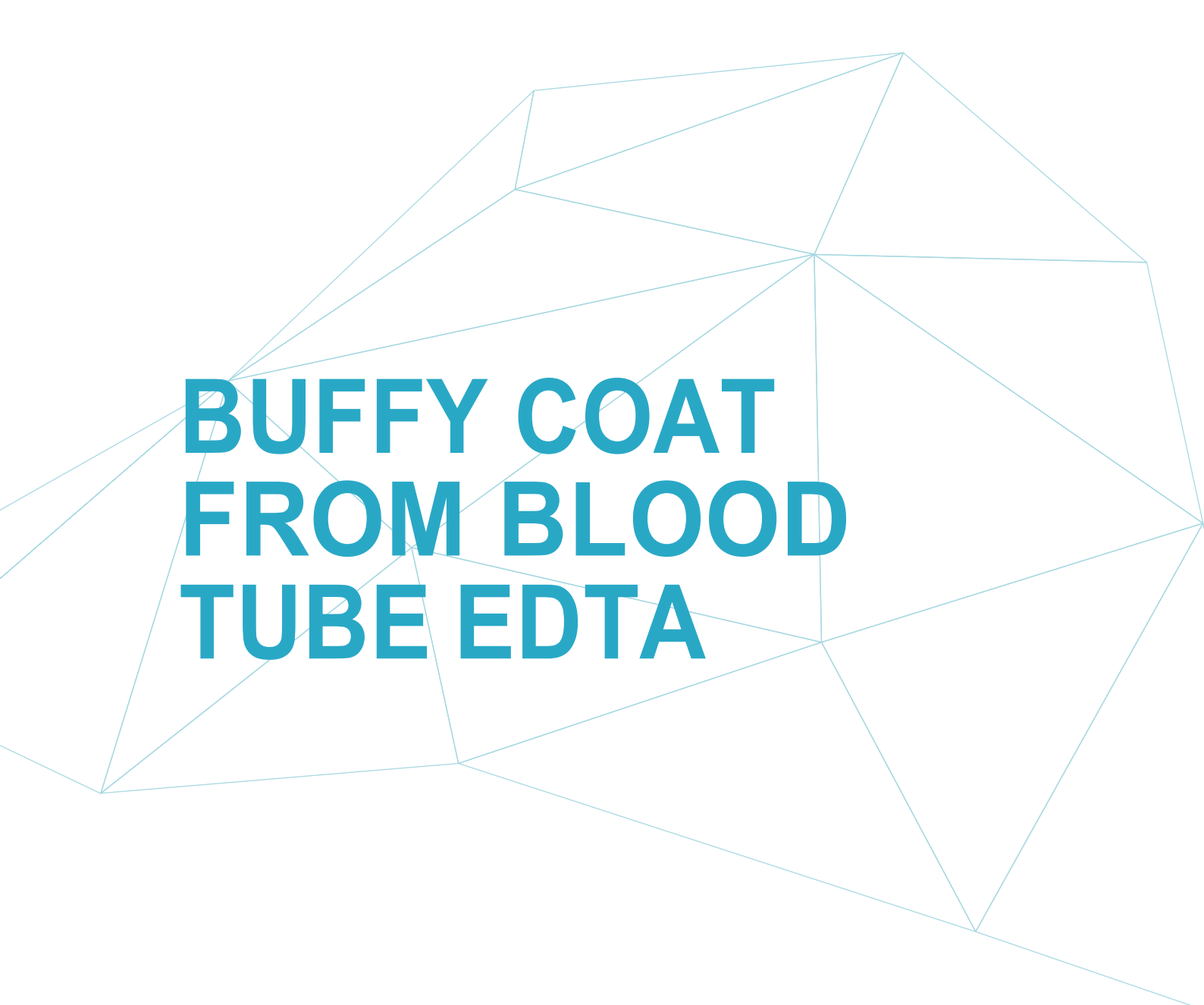


7.

Using a Pasteur pipette (Figure 2) transfer 5 serum aliquots (0.5 ml each) at the indicated vials in the Wilmut plate and store immediately at -80°C.

TOTAL: maximum 5 vials/patient/visit.
Always handle the Wilmut plate with the barcode on the right hand side.
Do not move any tube within the plate.
It is critical to maintain the order of the tubes.





BUFFY COAT FROM BLOOD TUBE EDTA

1. PURPOSE

The EDTA tube or BD Vacutainer® Plus plastic Blood tube (Figure 1) is an evacuated blood collection tube system containing K₂EDTA as an anticoagulant. This SOP describes the basic guidelines to use these tubes to collect the buffy coat from whole blood.

2. MATERIAL

- Routine venipuncture material.
- 1x BD Vacutainer® EDTA plastic whole blood tube (#368861, BD). Store tubes upright at room temperature and protect them from direct light.
- Centrifuge with swing-out head.
- Pasteur pipettes (not provided by the EFCLIF).

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided (SOP-0).

2.

Collect 4 ml of blood directly into EDTA-tube (1 EDTA 4 mL tube/ patient/visit).

3.

Gently invert the tube five times to mix anti-coagulant with blood.

4.

Centrifuge at 1500 RCF (g) for 10 min at 4°C in a horizontal rotor (swing-out head), (remember to use the appropriate balance tube).

5.

Discard the plasma fraction.

6.

Keep the original Vacutainer EDTA tubes with the cellular pellet at 4°C for the collection of the buffy coat.

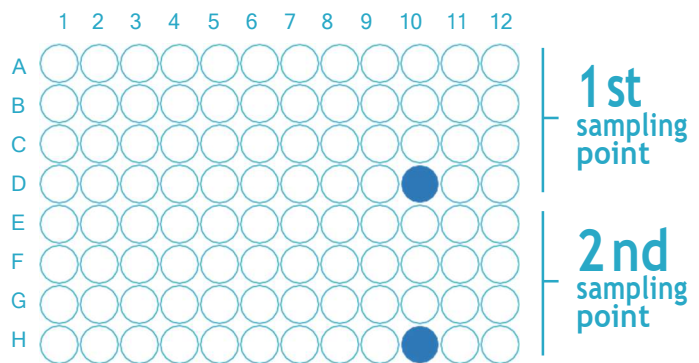
7.

For buffy coat collection, pick up the white thin cell fraction (~0.5 ml) just above the red cell cushion using a Pasteur plastic pipette (not supplied).



Transfer 1 buffy coat aliquot for the EDTA-tube (~0.5 ml each) at the indicated vial in the Wilmut plate and store immediately at -80°C.

TOTAL: 1 vial/patient. Always handle the Wilmut plate with the barcode on the right hand side. Do not move any tube within the plate. It is critical to maintain the order of the tubes.



BUFFY COAT AND PLASMA FROM BLOOD TUBE CITRATE

1. PURPOSE

The citrate tube or BD Vacutainer® glass plasma tube (Figure 1) is an evacuated blood collection tube system containing a buffered sodium citrate solution as an anticoagulant. This SOP describes the basic guidelines to use these tubes to collect plasma samples and buffy coats from whole blood.

2. MATERIAL

- Routine venipuncture material.
- 2X BD Vacutainer® citrate plastic whole blood tube (#363079, BD). Store tubes upright at room temperature and protect them from direct light.
- Centrifuge with swing-out head.
- Pasteur pipettes (not provided by the EFCLIF).
- Clean 15 ml tube (not provided by the EFCLIF).

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided (SOP-0)

2.

Collect 4 ml of blood directly into CITRATE-tube (2 Citrate-tubes /patient/visit) (Figure 1).



Figure 1

3.

Gently invert the tube five times to mix anti-coagulant with blood.

4.

Centrifuge at 1500 RCF (g) for 10 min at 4°C in a horizontal rotor (swing-out head), (remember to use the appropriate balance tube).

5.

Collect the plasma fraction (Figure 2) and transfer it into a clean 15 ml tube with a sterile Pasteur plastic pipette (not supplied) (Figure 3).

6.

Keep the tube with the cellular pellet at 4°C for the collection of the buffy coat

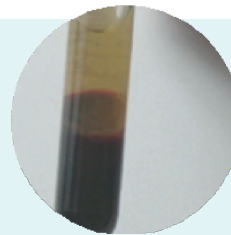


Figure 2



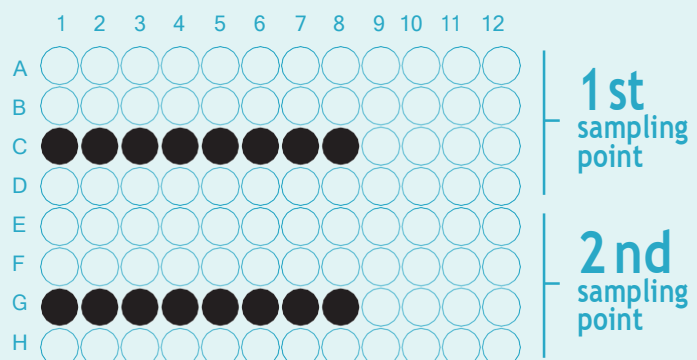
Figure 3

7.

Centrifuge plasma in the 15 ml tube at 2500 RCF (g) for 15 min at 4°C, (remember to use the appropriate balance tube).

8.

Transfer plasma aliquots (0.5 ml each) (maximum 4 for each CITRATE-tube) at the indicated vials in the Wilmut plate and store immediately at -80°C. **TOTAL: maximum 8 vials/patient/visit.**



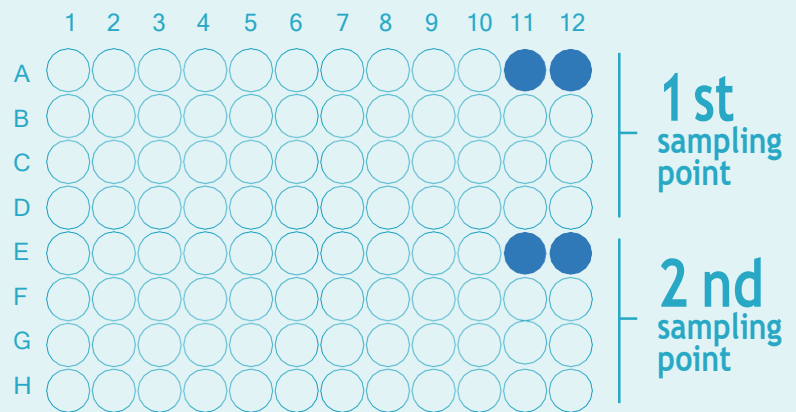
9.

For buffy coat collection, pick up the white thin cell fraction (~0.5 ml) just above the red cell cushion (Figure 2) using a Pasteur plastic pipette (not supplied).

10.

Transfer 1 buffy coat aliquot for each CITRATE-tube (~0.5 ml each) at the indicated vial in the Wilmut plate and store immediately at -80°C.

TOTAL: 2 vials/patient/visit.





PLASMA FROM BLOOD TUBE LI-HEPARIN

1. PURPOSE

The heparin tube or BD Vacutainer® Plus plastic plasma tube (Figure 1) is an evacuated blood collection tube system containing lithium heparin as an anticoagulant. This SOP describes the basic guidelines to use these tubes to collect plasma samples from whole blood.

2. MATERIAL

- Routine venipuncture material.
- 1 BD Vacutainer® LiHeparin plastic whole blood tube (#368884, BD). Store tubes upright at room temperature and protect them from direct light.
- Centrifuge with swing-out head.
- Pasteur pipettes (not provided by the EFCLIF).
- Clean 15 ml tube (not provided by the EFCLIF).

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided (SOP-0).

2.

Collect 4 ml of blood directly into HEPARIN-tube (1 Li-HEPARIN-tube/patient/visit) (Figure 1).



Figure 1

3.

Gently invert the tube five times to mix anti-coagulant with blood.

4.

Centrifuge at 1500 RCF (g) for 10 min at 4°C in a horizontal rotor (swing-out head) (remember to use the appropriate balance tube).

5.

Collect the plasma fraction and transfer it into a clean 15 ml tube with a sterile Pasteur plastic pipette (not supplied).

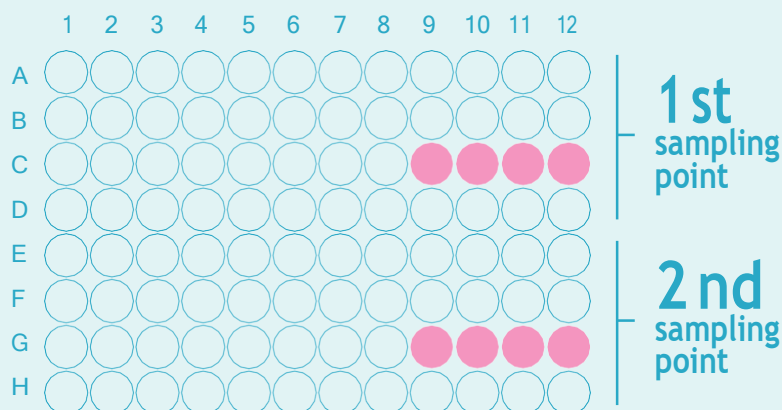
6.

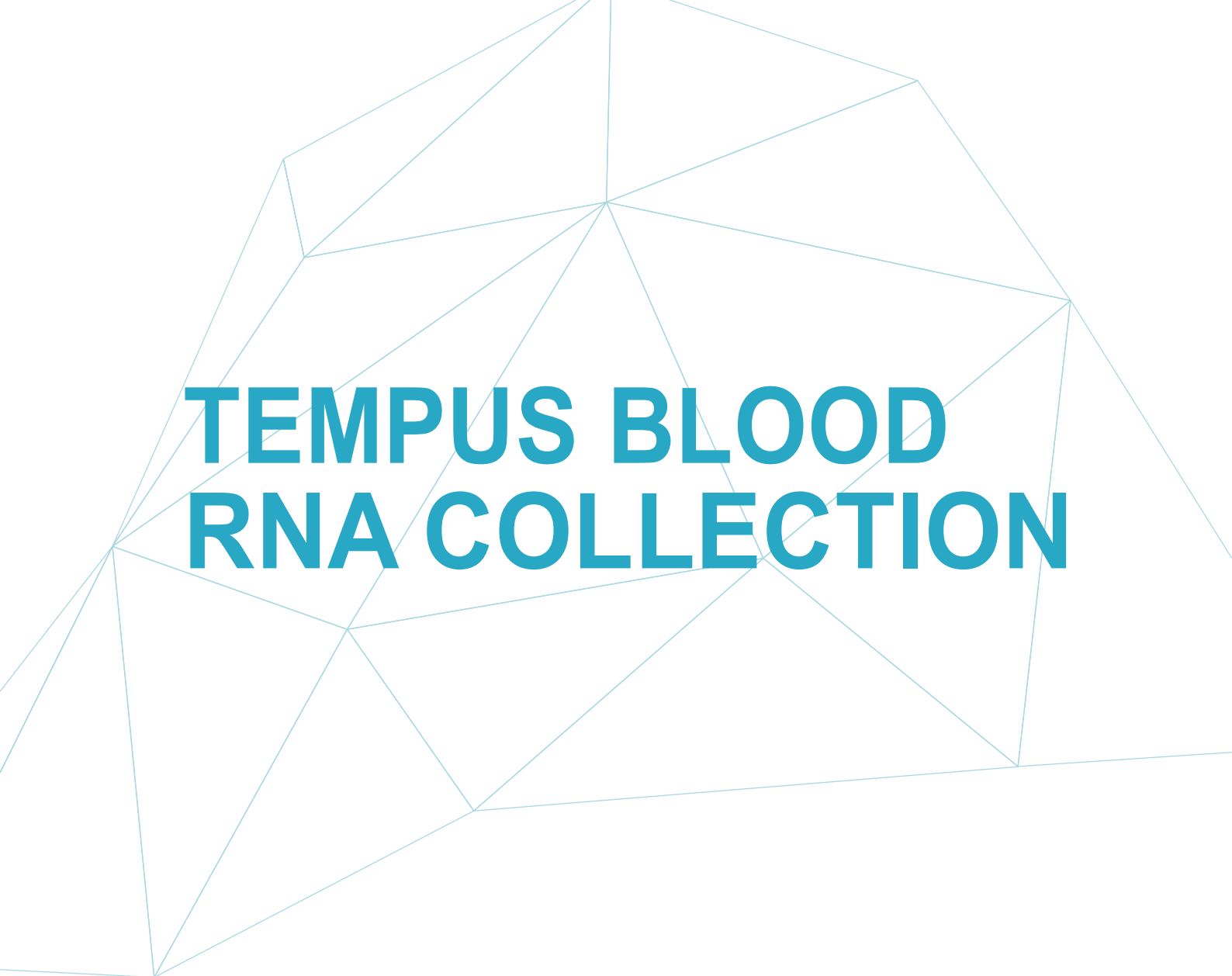
Centrifuge plasma at 2500 RCF (g) for 15 min at 4°C.

7.

Transfer 4 plasma aliquots for each Li-HEPARIN-tube (0.5 ml each) at the indicated vials in the Wilmut plate and store immediately at -80°C.

TOTAL: maximum 4 vials/patient/visit.





TEMPUS BLOOD RNA COLLECTION

1. PURPOSE

Tempus™ Blood RNA Tubes (Figure 1) are used for the stabilization and isolation of total RNA from 3 ml of whole blood for gene expression analysis. This SOP describes the basic guidelines to use these tubes.

2. MATERIAL

- Routine venipuncture material
- Tempus™ Blood RNA Tubes (#4342792, ThermoFisher Scientific). Keep tubes at room temperature until use.

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided (SOP-0).

2.

Draw ~3 ml of blood directly into Tempus™ Blood RNA Tube.
1 Tempus-tube/patient/-visit.

3.

Shake the tube vigorously for 10-20 sec (favouring cell lysis).

4.

Store at -80°C as soon as possible.



Figure 1

URINE COLLECTION

1. PURPOSE

Urine tests provide important information regarding the body's system function including glucose metabolism, kidney function and different hormone levels. This SOP describes the basic guidelines to collect clean-catch urine samples.

2. MATERIAL

- Urine collection container (Figure 1)
- 15 ml conical bottom plastic tube able to withstand centrifugation (Figure 2)



Figure 1



Figure 2

3. PROCEDURE

1.

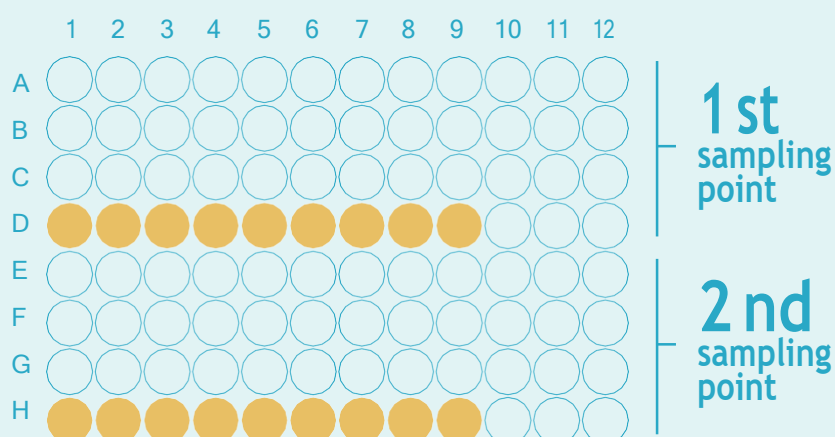
A clean-catch mid-stream urine sample can be collected at any time.

2.

Give the patient the urine collection container to collect at least half full container.

3.

Transfer 9 urine aliquots (0.5 ml each) with a Pasteur Pipette (not provided) at the indicated vials in the Wilmut plate and store immediately at -80°C .



4.

Collect ~9 ml of the remaining volume of urine with a Pasteur Pipette (not provided) and transfer it into a 15 ml conical bottom plastic tube. Store immediately at -80°C .

TOTAL: 1 tube/patient/visit + 9 vials.



SALIVA COLLECTION

1. PURPOSE

This SOP describes the basic guidelines to collect and store samples of saliva.

2. MATERIAL

- Cryovials (x2/patient) and cryoboxes(Figure 1).

3. PROCEDURE

1.

Ask the patient to let saliva collect in the mouth for at least 1 minute.

2.

Ask the patient to drool into the labeled cryotube.

3.

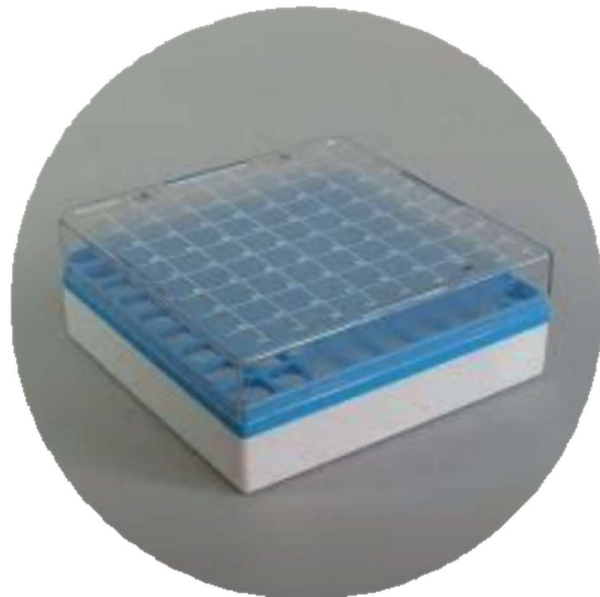
Repeat this process multiple times in order to collect at least 2 mL of saliva (TOTAL: 2 tubes/patient/visit).

4.

Store at -80°C as soon as possible.



CRYOTUBE



CRYOBOX 10*10

Figure 1



LIVER BIOPSY COLLECTION

1. PURPOSE

This SOP describes the basic guidelines to collect and store a liver biopsy when liver transplantation is performed.

2. MATERIAL

- Cryovials (x1/patient) and cryoboxes (Figure 1)
- Bottle Allprotect tissue reagent (Qiagen).
- Material and reagents needed for histological process (not supplied).

3. PROCEDURE

1.

Take a piece of liver immediately before the clamps are placed and the liver is removed from the recipient. After liver biopsy is obtained, divide the specimen in two parts.

2.

Place one half in a labeled cryovial with Allprotect® tissue reagent (Qiagen) for immediate stabilization of DNA, RNA and proteins (using the pump, dispense at least the minimum amount to submerge completely the specimen, one push on the pump is sufficient [approximately 500µL]). The stabilized tissue is stored at 15-25°C for up to 3 days, incubated overnight at 2-8°C and then, transferred to -80°C at the correct position in the cryobox provided. **TOTAL: 1 cryotube/patient.**

3.

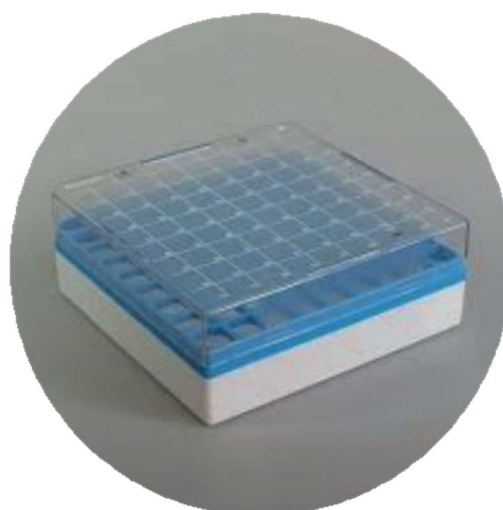
Place one half in formaldehyde for classical histological assessment (processing by the local histopathological department).

TOTAL: 1 paraffin block/patient.

At the end of the process, please label the paraffin block with the patient ID (center and patient number). It is important to avoid other information written in the block. Register the codification in the biobank form at the eCRF.

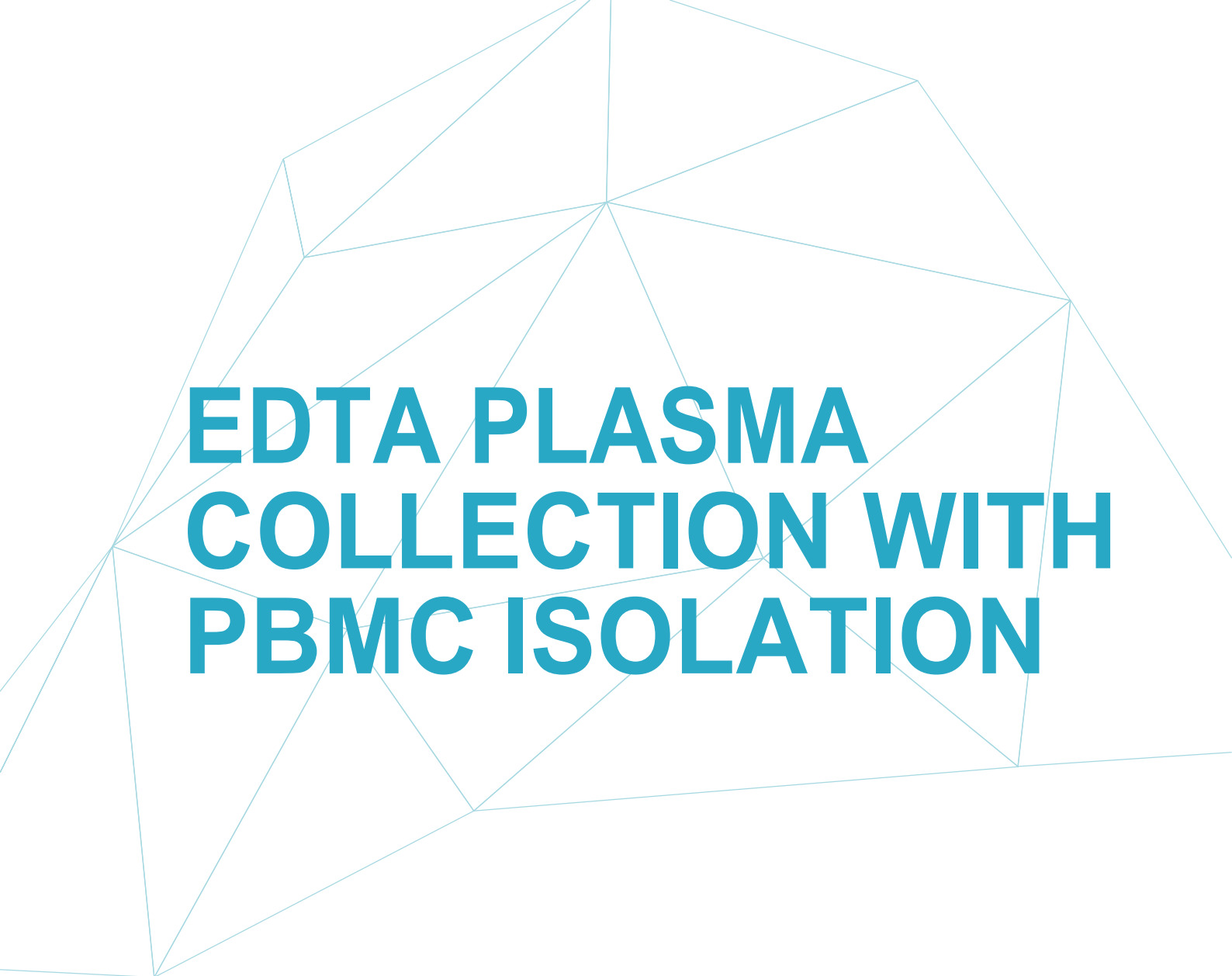


CRYOTUBE



CRYOBOX 10*10

Figure 1



EDTA PLASMA COLLECTION WITH PBMC ISOLATION

1. PURPOSE

This Standard Operating Procedure (SOP) describes the basic guidelines to collect EDTA plasma and to isolate peripheral blood mononuclear cells (PBMCs).

2. MATERIAL

- Routine venipuncture material.
- 2 EDTA Tubes 10 mL.
- 2 Prefilled Leucosep Tubes.
- Cryotubes.
- Fetal Calf Serum (FCS).
- DMSO.
- DPBS without calcium and magnesium (DPBS-/-).

3. PROCEDURE

1.

Perform the venipuncture according to the specific SOP provided.

2.

Collect blood directly into EDTA-tube (2 EDTA 10 mL tubes/patient/visit).

3.

Gently invert the tube five times to mix anti-coagulant with blood.

4.

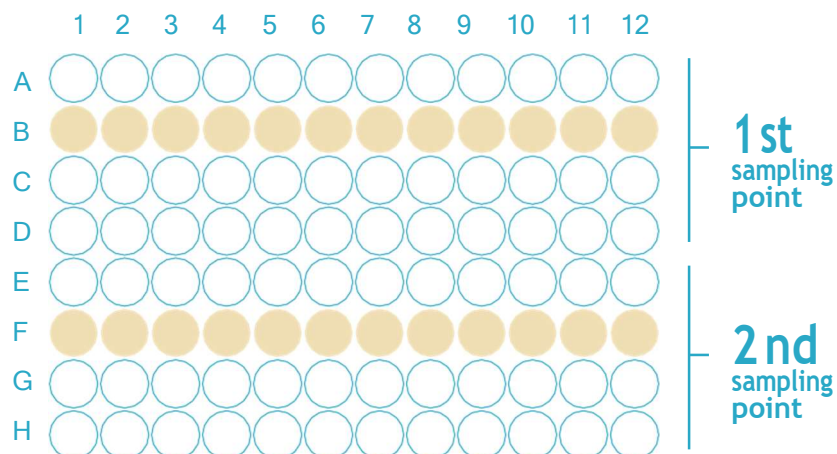
Centrifuge at 2000 RCF (xg) for 10 min at room temperature in a horizontal rotor (swing-out head) with break off, (remember to use the appropriate

5.

After centrifugation, the tube is ready for the collection of EDTA plasma and PBMC.

For EDTA plasma:

1. Collect the plasma fractions from each tube with a sterile Pasteur plastic pipette (not supplied) and transfer them into a clean 15 ml tube (not supplied). The plasma from the 2 EDTA-tubes are pooled. Leave 1 ml of plasma in the original tubes not to disturb the blood with the pipette.
2. Centrifuge the plasma in the 15 ml tube at 2500 RCF (g) for 15 min (remember to use the appropriate balance tube).
3. Use a clean Pasteur pipette to transfer plasma aliquots (0.5 ml each) at the indicated vials in the Wilmut plate and store immediately at -80°C. TOTAL: maximum 12 vials/patient/visit.



For PBMC isolation:


1. Dilute the pelleted blood with DPBS until reaching the original volume of blood.
2. Gently invert tube 5 times to mix blood with DPBS -/-.
3. Fill two pre-filled 12 ml LEUCOSEP tubes touching the side of the tube with the Pasteur pipette, keeping the tube vertical.



4. Centrifuge both tubes at 1000 rcf (x g) for 10' at room temperature, in a swinging bucket rotor with break off.
5. After centrifugation collect the layer above the porous barrier with a Pasteur pipette carefully in a 15 ml falcon tube (one for each LEUCOSEP tube).



6. Add 10 ml of phosphate-buffered saline (DPBS) to the falcon tubes containing the PBMCs and centrifuge for 10 minutes at 330 rcf (x g) at room temperature.
7. During centrifugation prepare the 3 labelled cryovials by adding 500 ul of freshly mixed FCS-DMSO 20% to each.
8. After the centrifugation discard the supernatant and resuspend cell pellet in 1.5 ml FCS.
9. Slowly add 0.5 ml of cell suspension to each of the 3 cryotubes filled with FCS-DMSO 20% (end concentration of DMSO in cell suspension is 10%).
10. Place cryotubes in Mr. Frosty filled with isopropanol for 24 h in a -80°C freezer. After 1 day transfer cells to normal box and leave in -80°C freezer and avoid thawing samples!



SAMPLE LABELLING

1. PURPOSE

This SOP describes the basic guidelines to label and identify all the samples correctly.

2. MATERIAL

- Labels.
- Templates for racks and cryoboxes.
- Tubes and cryotubes.
- Wilmut plates.
- eCRF platform.

3. GENERAL OVERVIEW

- Any sample should be discarded during the study. All the samples (including the ones from the screening failure patients) should be sent at the end of the study.
- Samples shouldn't be manually-labelled.
- Templates for racks and cryoboxes should be sent to the CHANCE Study team when completed. It is mandatory to send them before sample shipment.
- When the study finishes, samples will be sent to the regional coordinator's facilities, where they will be inventoried and stored in order to maintain the traceability but never processed or aliquoted.
- In case any technical issue happens, like a freezer break-down or a deviation in temperature maintenance, the CHANCE Study team should be contacted in order to take the corrective measures as soon as possible.

4. PROCEDURE

4.1. Labelling for tubes and cryotubes.

- A) For each sample, two identical labels are supplied (Figure 1). Every code is 10 characters long and starts with CH.



Figure 1. Example of supplied labels (one for the tube and one for the paper).

- B) Please be aware that one of them is designed to be stuck on the tube, and the other is designed to be stuck on the papers (templates) supplied (Figure 2).

	1	2	3	4	5
A	Date:	Date:	Date:	Date:	Date:
	Please stick here the label	Please stick here the label	Please stick here the label	Please stick here the label	Please stick here the label
B	Date:	Date:	Date:	Date:	Date:
	Please stick here the label	Please stick here the label	Please stick here the label	Please stick here the label	Please stick here the label

Figure 2. Screenshot of a part of a template.

- C) When collecting the samples, the correct label should be stuck on the tube, and the other on the specific template (rack or cryobox depending on the type of sample isolated in each case).
- D) Samples should be stored in the same position at the rack or cryobox than the one the label is stucked on, so traceability can be guaranteed.
- E) The collection date should be written on the template using the specific field for it.
- F) The sample code (CHXXXXXXXX) should be introduced in the specific field for it at the biobank form at the eCRF (Figure 3). Whenever possible, the biobank form should be completed at the same time of sample collection. Otherwise, the sooner the better: please be aware that labels have no patient id so it is very important to minimize this length of time in order to maintain traceability.

2. Tempus tube collected (Blood RNA) Yes No

Tempus tube material collected

Label code

Collection process information

Time from sample collection to storage at -80°C Less or equal 1 hour More than 1 hour

Figure 3. Screenshot of the biobank form in the eCRF registering the specific code of the sample (the same than in the label).

4.2. Labelling for wilmot plates.

- A) Tubes should not be moved from the initial position within the plate or to another plate. Empty tubes should be removed from the plate always after having collected all types of sample.
- B) Use this procedure to use the transit wilmot plate:
- Use the PCR plate to move all the tubes from the real plate (example AAA12345) to the transit plate (without code). Be aware of putting the tubes in the correct position (it is quite easy to invert the tubes).
 - You can fill the tubes used in the 1st sampling point (rows A-D).
 - Transfer manually the full tubes to the real plate (AAA12345 in this example) and move it immediately to the -80°C freezer (rows A-D). Now you have the real plate frozen with the samples from the 1st visit and the transit plate with the rest of the tubes at room temperature ready to use in the 2nd visit (rows E-H).
 - Fill the tubes with samples from the 2nd visit (rows E-H).
 - Transfer manually the tubes to the real plate. Now you have the real plate with the tubes in the same positions with all the samples in the freezer and the transit one empty ready to use again!
- C) The colour code in wilmot taps should be followed.
- D) Please note that tube codes are related to the plate they are located in. The tube code is the plate code followed by two numbers indicating the position of the tube inside the plate. For example, in plate AAA123345, the tube in position A1 has the code AAA1234501, tube in position A2 is AAA1234502... tube in position H11 is AAA1234595 and tube in position H12 is AAA1234596.
- E) Specific SOPs for each sample collection should be followed to store each of them in the specific tube(s) for it.
- D) The tube code(s) should be introduced in the eCRF at the biobank form (Figure 4) for each type of sample. Whenever possible, the biobank form should be completed at the same time of sample collection. Otherwise, the sooner the better: please be aware that labels have no patient id so it is very important to minimize this length of time in order to maintain traceability.



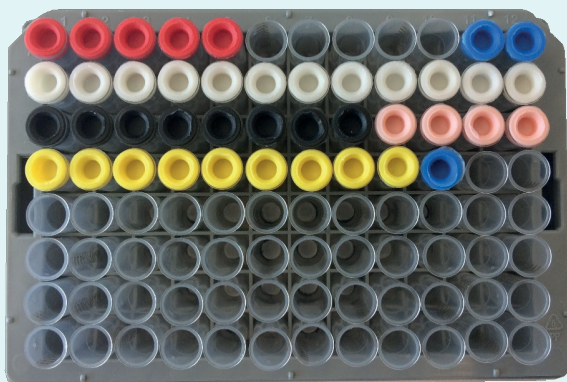
Wilmut plate code	<input type="text" value="AAA12345"/>
Wilmut sampling point	<input checked="" type="radio"/> 1st <input type="radio"/> 2nd
Cryobox plate number (for saliva)	<input type="text" value="1"/>
1. Blood sample collection	<input checked="" type="radio"/> Yes <input type="radio"/> No
Type of blood sample	<input checked="" type="radio"/> Peripheral venous <input type="radio"/> Central venous <input type="radio"/> Arterial <input type="radio"/> Other
Collection date	<input type="text" value="7/1/2020"/> 
Time of collection	<input type="text" value="1:14 PM"/> 
Serum sample collected	<input checked="" type="radio"/> Yes <input type="radio"/> No
Serum sample information	
Number of aliquots collected	<input type="text" value="5"/> ▼
Rack Code	<input type="text" value="AAA1234501"/>
Rack Code	<input type="text" value="AAA1234502"/>
Rack Code	<input type="text" value="AAA1234503"/>
Rack Code	<input type="text" value="AAA1234504"/>
Rack Code	<input type="text" value="AAA1234505"/>
Time from sample collection to aliquoting	<input checked="" type="radio"/> Less or equal 1 hour <input type="radio"/> More than 1 hour
Time from sample collection to aliquoting	<input checked="" type="radio"/> Less or equal 1 hour <input type="radio"/> More than 1 hour

Figure 4. Screenshot of the biobank form in the eCRF registering the specific codes of the wilmut plate used for isolating this serum sample.

5. EXAMPLE OF SAMPLE LABELLING

A. WILMUT

Once all samples are collected in one visit the plate will look like this:



Please note that the code in each tube is the code of the plate followed by two numbers indicating the position of the tube inside the plate.

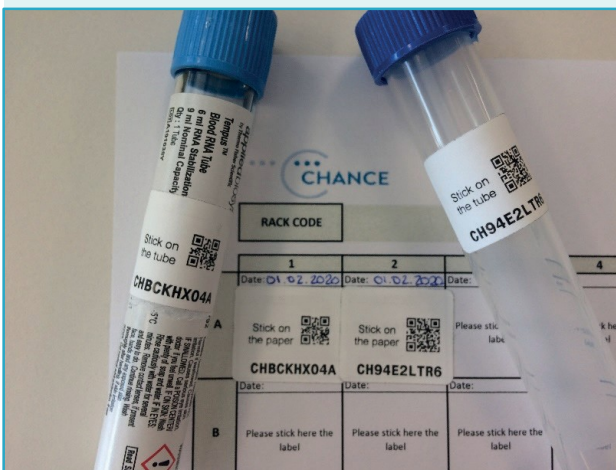
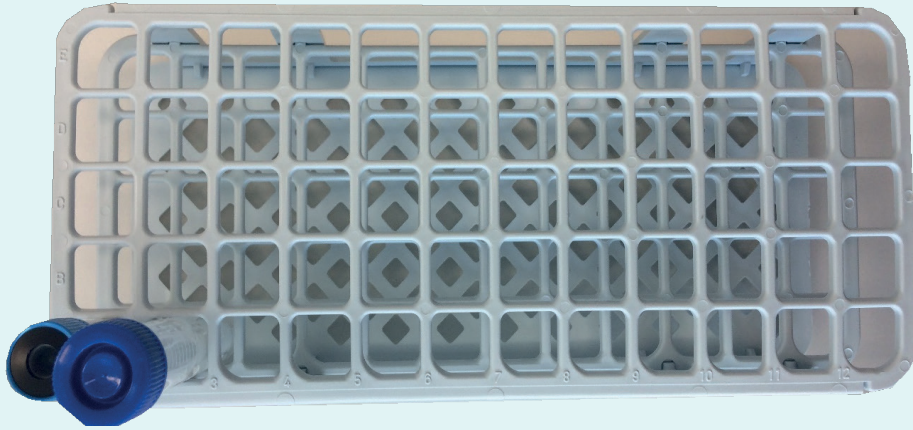


Please do not move the tubes within the plate or between plates (it would make the process more difficult).

In the figure, the code of the tube A12 (in the position 12) is AAA6797412 (AAA67974 code of the plate plus 12 because of its position).

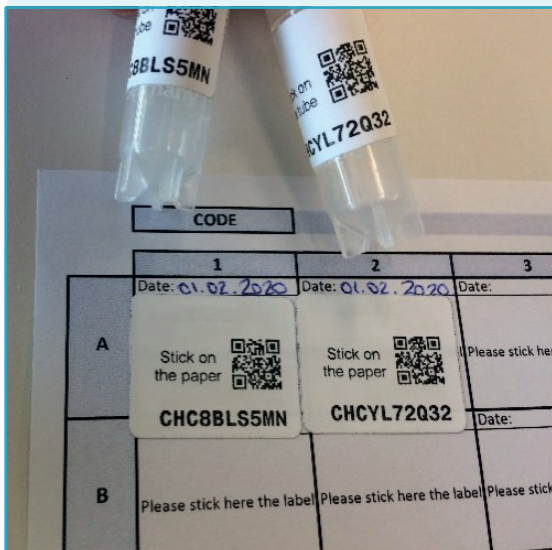
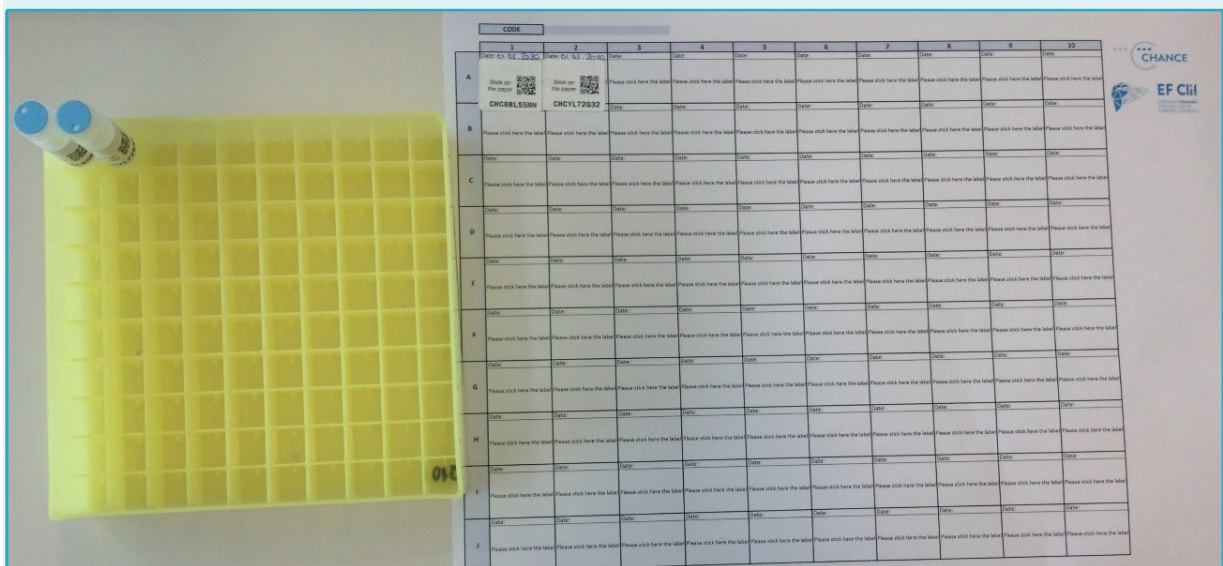
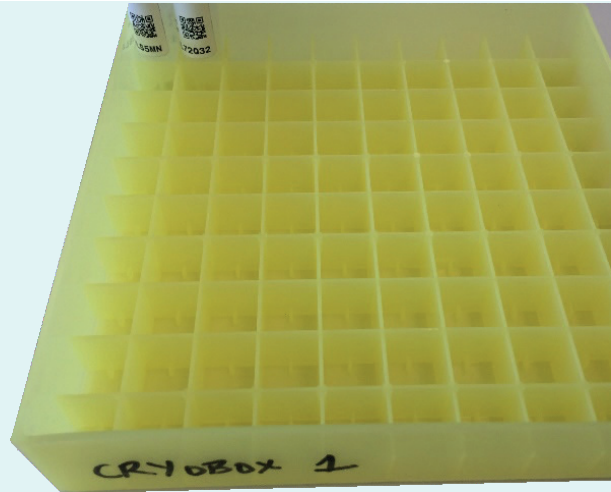


B. RACKS



Please remember to stick both labels (in the tube and the template) and write the date in the papersheet. Put the tubes in the same position than specified in the papersheet.

C. CRYOBOX



Please remember to stick both labels (in the tube and the template) and write the date in the papersheet. Put the cryotubes in the same position than specified in the papersheet.

D. REGISTRATION IN THE eCRF.

BIOBANK SAMPLES COLLECTION (BB)

Samples obtained Yes No

Biobank samples collection

Patient code


Wilmot plate code


Wilmot sampling point 1st 2nd

Cryobox plate number (for saliva)

1. Blood sample collection Yes No

Type of blood sample Peripheral venous
 Central venous
 Arterial
 Other

Collection date 

Time of collection 

Serum sample collected Yes No

Serum sample information

Number of aliquots collected

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Time from sample collection to aliquoting Less or equal 1 hour More than 1 hour

Time from aliquoting to storage at -80°C Less or equal 1 hour More than 1 hour

Type of Plasma sample collected

EDTA Yes No

EDTA material(s) collected

EDTA-Plasma Yes No

Number of aliquots collected

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

EDTA-Buffy coat Yes No

Rack Code

Li-heparin Yes No

Li-heparin material(s) collected

Number of aliquots collected

Rack Code

Rack Code

Rack Code

Rack Code

Collection process information

Time from collection of blood to the first centrifugation Less or equal 1 hour More than 1 hour

Time from aliquoting to storage at -80°C Less or equal 1 hour More than 1 hour

2. Tempus tube collected (Blood RNA) Yes No


Tempus tube material collected

Label code

Collection process information

Time from sample collection to storage at -80°C Less or equal 1 hour More than 1 hour

3. Urine sample collected Yes No

Collection date 

According to tube(s) type

Wilmut tube Yes No

Wilmut tube material(s) collected

Number of aliquots collected

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code

Rack Code


Rack Code

10 mL tube Yes No

10 mL tube material collected

Label code

4. Saliva sample collected Yes No

Collection date 

Saliva sample material(s) collected

Number of aliquots collected

Label Code

Label Code

5. PBMC sample collected Yes No

Save and next

Exit without save



EF Clif

EUROPEAN
FOUNDATION
FOR THE STUDY
OF CHRONIC
LIVER FAILURE