
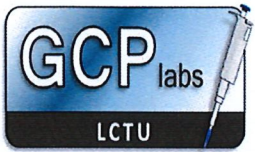


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|   | | <p align="center">LCTU GCPLab</p> <p align="center">Standard Operating Procedure</p> <p align="center">KIT PREPARATION FOR THE LPRG PANCREAS TISSUE BANKS</p> | |
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1. WHO?

This Standard Operating Procedure (SOP) applies to all staff delegated to build kits for the collection of samples for the LPRG research tissue banks and studies.

This SOP also applies when a student on a higher degree course will build sample collection kits for a research project under the supervision of the GCP Lab Directors.

2. BACKGROUND

The collection of human tissue is governed by the Human Tissue Act (2004) and EU Directives on research governance. It is the responsibility of each individual to have read and understood the relevant documentation in order to abide by the regulations.

3. PURPOSE

The purpose of this SOP is to describe the process involved in kit creation, storage and dispatch for the LPRG biobanks and studies.

4. SCOPE

This SOP applies to kits being made for the Biobanks and studies within the LPRG.

5. PROCEDURE

5.1 RESPONSIBILITY

It is the responsibility of the:

- All staff inducted into the LPRG laboratory who have been trained in kit building and delegated by the Operational Director to build the kits.
- It is the responsibility of the staff delegated to building the kit, to record all processes involved in the creation and dispatch of the kit on LIMS.
- It is the responsibility of the person designated to QC the kits to ensure that all the components are present and labelled correctly.

5.2 PROTOCOL

There are different types of LPRG kits:

- Acute Pancreatitis Biobank: A, B, C, P, Q and S kits
- Chronic Pancreatitis Biobank Kit
- Control Biobank Kit
- Health Volunteer kit

1. Kits must be prepared by 2 or more people. One person must prepare the kits and the other must perform a quality control check. The same person must not prepare kits and perform the quality control (i.e. four eye view).

2. Ensure all the required consumables are present and fit for purpose. All components in the kits must have been stored according to the manufacturer's guidelines.
3. Ensure protective lab coats are worn by all persons preparing kits.
4. Record all procedures involved in the kit creation, QC and dispatch process on LIMS according to the **SOP GCLPRPS011 – Use of LIMS to Record Kit Construction, QC, Storage and Dispatch**.
5. Each pertaining kit control form and kit components must have a bar-coded label to uniquely identify the kit and all its components. Check the named database for the next available kit number to be used.
6. LIMS will record the following:
 - Kit number
 - Description
 - Date the kit was created
 - Kit expiry date
 - Person who assembled the kit
 - Person performing quality control
 - Location kit was created.
7. Assemble each kit and label all the components with the unique kit specific label generated by LIMS. The assembled kits must be given to another member of staff trained in kit building to perform a QC check.
8. The quality control check is to ensure that the items are correctly labelled and the correct number of items is present in each kit. If there is an error in the kits then they should be returned to the person who created the kit, corrected by them and re-submitted for QC. This should be noted in the person's laboratory notebook and recorded on LIMS.
9. All quality control notes should be made in the comments section on LIMS.
10. All kits should be stored in the LPRG Research Laboratory 1 (Rm3:302A).
11. When the kits are being given to a research fellow for sample collection, the dispatch information is to be updated on LIMS (see **SOP GCLPRPS011 – USE of LIMS to Record Kit Construction, QC, Storage and Dispatch**).

6. ABBREVIATIONS

| | |
|-------------|------------------------------------------|
| GCP | Good Clinical Practice |
| GCLP | Good Clinical Laboratory Practice |
| LIMS | Laboratory Information Management System |
| LPRG | Liverpool Pancreatitis Research group |
| QC | Quality Check |
| SOP | Standard Operating Procedure |

7. OTHER RELATED PROCEDURES AND DOCUMENTS

SOP:

GCLPRPS011 Use of LIMS to Record Kit Construction, QC, Storage and Dispatch

8. APPENDIX

8.1 Appendix 1: Example of a Kit Building Control Table

| Biobank/ Study Name | LIMS name | Components |
|---------------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) SST (3.5ml) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Consent Form Patient Information Sheet Check list |
| | pPBRU-B | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) SST (3.5ml) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list |
| | pPBRU-C | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) SST (3.5ml) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list Consent form Patient information sheet |
| | pPBRU-Ap | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) Na Ci 94.5ml) SST (3.5ml) |

| | | |
|--|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | BJ (7ml) 4 x Falcon (Q1-4) eppendorf PBM 9 x P (Tru, x2 Iso cont, 3 x Test, FMO, golgi, ISO) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list Consent form Patient information sheet |
| | pPBRU-Bp | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) Na Ci 94.5ml) SST (3.5ml) BJ (7ml) 4 x Falcon (Q1-4) Eppendorf PBM 9 x P (Tru, x2 Iso cont, 3 x Test, FMO, golgi, ISO) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list Consent form Patient information sheet |
| | pPBRU-As | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) SST (3.5ml) 3 x Falcon tube: B1, B2 and P Falcon U 12 x Falcon (S1-7 and S11-16) 2 x Eppendorf (S9, S10) Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list Consent form Patient information sheet |
| | pPBRU-Bs | Needle |

| | | |
|--|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) SST (3.5ml) 3 x Falcon tube: B1, B2 and P Falcon U 12 x Falcon (S1-7 and S11-16) 2 x Eppendorf (S9, S10) Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list |
| | pPBRU-Aps | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) Na Ci 94.5ml) SST (3.5ml) BJ (7ml) 4 x Falcon (Q1-4) 12 x Falcon (S1-7 and S11-16) 2 x Eppendorf (S9, S10) eppendorf PBM 9 x P (Tru, x2 Iso cont, 3 x Test, FMO, golgi, ISO) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) 2 x Nunc (white insert) 5 x Nunc (green insert) Check list Consent form Patient information sheet |
| | pPBRU-Bps | Needle PAXgene BRT (2.5ml) EDTA (10ml) EDTA (4ml) Na Ci 94.5ml) SST (3.5ml) BJ (7ml) 4 x Falcon (Q1-4) 12 x Falcon (S1-7 and S11-16) 2 x Eppendorf (S9, S10) Eppendorf PBM 9 x P (Tru, x2 Iso cont, 3 x Test, FMO, golgi, ISO) 3 x Falcon tube: B1, B2 and P Falcon U Bijou 8 x Nunc (red inserts) 5 x Eppendorf (Ery) 5 x Eppendorf 5 x Eppendorf (p) |

| | | |
|------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | 2 x Nunc (white insert) 5 x Nunc (green insert) Check list |
| Chronic Pancreatitis Biobank | pPancRotaP | EDTA K2 (9ml) Serum Z (9ml) Monovette needle 1 Urine pot (250ml) 6 x 1.8ml Nunc tubes (Inserts- Red) 4 x 1.8ml Nunc tubes (inserts- White) 6 x 1.5ml Eppendorf tubes 6 x 1.8ml Nunc tubes (Cryovial) (Inserts- Green) 50ml x Falcon tube (Falcon T) 50ml x Falcon tube (Falcon A) Worksheet |
| Control Blood | pPancRota C | EDTA (9ml) Serum Z (9ml) Monovette needle 6 x 1.8ml Nunc tubes (red inserts) 4 x 1.8 ml Nunc tubes (white inserts) 6 x 1.5 ml Eppendorf tubes Work sheet Consent form |
| Healthy volunteer | pHV-PBRU-E | Needle 5 x EDTA Falcon Worksheet Consent |
| | pHV-PBRU-S | Needle 6 x SST (8mls) Worksheet Consent |