

SOP_PMT-STUDY: UNIQUE IDENTIFIER STICKY LABEL PROCEDURES

Sticky label sheets are available for download at the PMT study virtual research environment (VRE) (https://pmt.nesc.gla.ac.uk:8443/pheo_ppgl/). Each subject enrolled into the study is automatically assigned a unique identifier (see Handbook of Clinical Studies SOP CNS-C-01) once a new electronic case report form (eCRF) record is created for that subject. Sticky label sheets — specific for each subject according to the unique identifier — then become available for download.

There are two sticky label sheets available for download: one for use in outpatient clinics and 2. the other for use by the laboratory. Sheets should be downloaded and printed on the specified sticky label sheets (see Handbook of Clinical Studies SOP CNS-D-01).

Outpatient clinic sticky labels

The outpatient sticky labels are used at Dresden for maintaining records of consent, patient visit files (see Handbook of Clinical Studies SOP CNS-B-01) and for labeling blood tubes and urine collection containers at the clinic, prior to transport to the laboratory for further processing (i.e., for blood centrifugation, urine volume measurements and aliquot preparation). These labels may also be used by other participating centers for similar purposes. Otherwise alternative procedures should be established for record keeping and channeling of research and routine samples. All labels should be dated using indelible ink according to the dates that patients are consented and specimens collected.

At Dresden blood and urine specimens are collected for both routine patient care and research purposes. The presence of these labels on blood tubes and urine containers, in addition to the standard in-house patient labels, serves to alert the laboratory staff that samples must be separated into different aliquots for routine and research purposes. The plasma and urine aliquots separated for research purposes are identified using only the laboratory specific labels described below.

Procedures for use of laboratory-specific sticky labels.

Laboratory sticky labels are provided for research samples that are either stored as banked samples at participating sites or shipped to the Dresden laboratory for analyses. These labels are not for use with blood collection tubes or urine containers. All labels should be dated using indelible ink according to the dates that specimens are collected.

All sticky labels are colour-coded according to the phase of the study (i.e., Phase 1 to 4) or in other cases according to the type of sample collected (i.e., tumour tissue, DNA, follow-up plasma samples). Laboratory sticky labels are also distinguished according to the type of sample to be banked or shipped. Samples are also distinguished in most, but not all cases, by the type of collections and/or analytes to be measured (MET, metanephrines; DY, day urine collection; ON, overnight urine collection; 24, 24 hour urine collection; CLON BL, clonidine baseline sample; CLON 180, 180 minute post-clonidine sample; CAT, catecholamines).

Phase 1: For phase 1 there are labels for two tubes of heparinized plasma, one of which should be shipped from outside centers to Dresden and the other banked locally. The same applies to all other duplicate labeled samples. There are also multiple labels for phase 1 urine collections. At Dresden, urine is collected into separate day and night collection containers. These are used to assist in establishing reference intervals for phase 1 overnight collections, but samples are also aliquoted into 24-hour tubes (URIN 24 MET) for phase 1 measurements. For centers outside of Dresden, the 24-hour urine label (URIN 24 MET) represents the most appropriate and simplest to utilize. The day (DY) and overnight (ON) labels can be ignored. Additional blank labels can be used for storage of extra sample, when available.

Phase 2: For phase 2, the duplicate baseline and 180 minute samples for clonidine are for purposes of measuring both catecholamines and metanephrines. Therefore, there must be well in excess of 2 mL of plasma in each of these tubes. Urine samples collected for overnight metanephrines and 24 hour catecholamines in phase 2 can be collected according to the procedure outlined above for urine samples collected at Dresden for phase 1. Alternatively 2 separate collections can be employed (e.g., one overnight and one full 24 hour collection).