DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

DZHK-SOP-B-01

Collection of Biomaterials from Blood and Urine

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1 List of Abbreviations

Abbreviation	Full form
SOP	standard operating procedure
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung e.V.
BB	biomaterial bank
BD	Becton Dickinson AG
EDTA	ethylenediaminetetraacetic acid

2 Modifications to Previous Version

Section	Old Version	New Version
4	Table 1 for BD primary receptacles Serum: 8.5 ml Urine: 8.5 ml	Table 1 for BD primary receptacles Serum: 10.0 ml Urine: 11.0 ml
Annex	Biomaterial Collection Form - Basic Set *(Version 1.0)*	Biomaterial Collection Form - Basic Set, Version 1.1

3 Introduction

3.1 Purpose

The purpose of this standard operating procedure is to describe the process of collecting fluid biomaterials up to the point of transport to the laboratory (for further processing) in the context of DZHK projects (normally for a clinical study, registry or cohort) in order to set up a DZHK biomaterial bank under standardized conditions.

Core elements of this SOP appear on a grey background.

3.2 Terms and Definitions

Biomaterials include e.g. blood, urine, stool and tissue as well as the materials that result after processing (e.g. plasma, serum in aliquots as well as DNA, RNA and stem cells).

The term ***biomaterial bank (BB)*** should be understood as the storage of biomaterials as well as the storage of data on the quality attributes of the biomaterial and corresponding information. The biomaterials are to be stored at a temperature of at least -80°C (e.g. in a deep freezer or automated cryogenic storage system).

DZHK biomaterial denotes the biomaterial which is collected from every patient/test subject participating in a DZHK project (normally a clinical study, registry or cohort) and which becomes property of the DZHK and is hence subject to the DZHK Terms of Use. For blood, the quantity of biomaterial to be collected is calculated on the basis of the cross-study quantity and the study-specific quantity (DZHK basic quantity or DZHK study quantity), which must be processed and stored.

Cross-study biomaterials, which are collected independently of any concrete study, are referred to as ***DZHK Basic Sets***.

Study-specific biomaterials, which are additionally collected for the purpose of a concrete study, are referred to as ***DZHK Study Sets***.

3.3 Level of Quality

This SOP corresponds to Quality Level 2 of the DZHK.

DZHK Quality Levels	
Implementation	
Level 1	The examination is performed in accordance with the requirements laid down in the Guidelines of the German Medical Association on Quality Assurance in Medical Laboratory Testing.
Level 2	The examination is performed in accordance with the requirements of the SOP of the DZHK. The minimum requirements for ensuring the quality of the implementation and of the examiner are defined herein.
Level 3	The examination is performed in accordance with the requirements of the SOP of the DZHK and certification of the examiner: Determination of intra- and inter-observer variability (standard of epidemiological studies).

4 Background

Collection of Biomaterials

The collection, processing and storage of the DZHK basic set of biomaterials (see Table 1) are important steps in the pre-analytical process and must be performed in a standardized manner in accordance with the SOPs of the DZHK.

In scientific studies, various experimental approaches are used to examine human biomaterials (e.g. determination of standard laboratory values, metabolic or proteomic methods, DNA/RNA extraction, biomonitoring). Therefore, the methods used to collect, process and store the biomaterials have to be standardized in such a way that as many of the above-mentioned techniques as possible can still be applied even after long periods of storage.

Type of material, volume and quantity for the DZHK Biomaterial Bank

Processed biomaterials (= DZHK Basic Set) from every patient/test subject participating in a DZHK study, registry or cohort must be stored in a biomaterials bank. Primary receptacles from BD or Sarstedt must be used for the determination of blood parameters.

Table 1 Type of material, volume and quantity in the DZHK Basic Biomaterial Bank

	Primary receptacle	BD		Sarstedt	
		Volume	Quantity	Volume	Quantity
Basic Set	Serum	10.0 ml	1	7.5 ml	1
	EDTA	4.0 ml	2	7.5 ml	1
	Citrate	3.0 ml	2	3.0 ml	2
	Urine	11.0 ml	1	10.0 ml	1

5 Materials, Documents and Information Required

The collection set for collecting the DZHK Basic Set is centrally provided by Greifswald and contains:

- labelled primary receptacles and rack-mounted and labelled aliquot tubes
- Biomaterial Collection Form for the Basic Set with identification code for the basic collection set
- sticker (identification code) for the urine cup
- additional stickers (identification code without material ID)

Basic collection sets should be requested from

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Universitätsmedizin Greifswald
Ernst Moritz Arndt Universität Greifswald
Ferdinand-Sauerbruch-Straße
17475 Greifswald

Fax +49 3834 86 5502
E-mail: laborstudien.umg@uni-greifswald.de

The following are also required:

- DZHK patient/test subject identifier (**Basic Set Pseudonym**) for linking with the **Basic Collection Set ID** (identification code of the basic collection set)
- Instructions for patients/test subjects on sterile collection of urine (see information sheet “Collecting a Mid-Stream Urine Specimen”)

6 Workflow

6.1 Specific Requirements

The collection of biomaterials is carried out in accordance with local regulations. Deviations from the following requirements will not result in the exclusion of the patient/test subject from the study.

Collection of blood:

- Appropriate means of disposal for needles, swabs, etc.
- Period of rest in unaltered body position prior to blood collection: 5 minutes
- Site of collection on patient/test subject: cubital vein

- Tourniquet time < 1 minute
- Specimens should be drawn in the following order: serum, citrate, EDTA
- The tourniquet should be released once collection of blood has begun, i.e. when blood flow into the primary receptacle is visible
- No repeat clenching of the fist
- Invert immediately while exchanging the primary receptacles
- Store the primary receptacles vertically in the primary receptacle/tube rack

Collection of urine:

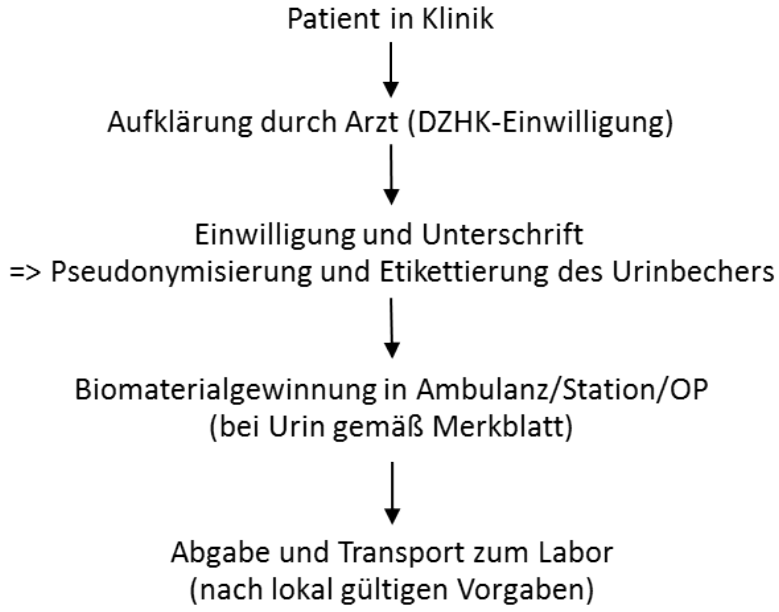
- Label the urine cup using the sticker intended for that purpose
- Inform the patient/test subject using the information sheet "Collecting a Mid-Stream Urine Specimen"
- Spontaneous urine collection
- Immediately after urine specimen is given: document the time the urine specimen was collected and the appearance of the urine on the Biomaterial Collection Form
- If patient/test subject is actively menstruating: Make a note of this on the Biomaterial Collection Form

Transport of biomaterials:

The primary receptacles along with the Biomaterial Collection Form and the aliquot tubes (rack) should be transported to the laboratory, if possible, within 60 minutes after collection of the biomaterial.

6.2 Flow Chart

Patient in clinic – Informative discussion with a doctor (DZHK consent) - Consent and signature => Pseudonymization and labelling of the urine cup - Collection of biomaterial in the outpatient clinic/ward/operating theatre (for urine, according to the information sheet) – Submission and transport to the laboratory (in accordance with local regulations)



➔ Document each individual step on the Biomaterial Collection Form

6.3 Handling Deviations

Deviations from the requirements listed under Section 6.1 (e.g. collection of blood from a site other than the cubital vein, tourniquet time longer than 1 minute) must be documented on the Biomaterial Collection Form.

7 Literature / Sources

Guidelines of the German Medical Association on Quality Assurance in Medical Laboratory Testing. Deutsches Ärzteblatt, 105 (7), 15 February 2008, pages A 341-355, most recently modified/amended in Deutsches Ärzteblatt 110 (39), 27 September 2013, page A 1822

8 Cross-References to Existing DZHK Documents

Type / SOP ID	**Title**
SOP-0105	*Acquisition of Personally Identifiable Information and Informed Consent (draft stage)*
DZHK-SOP-B-02	Biomaterial Processing Basic Set

9 List of Contributors

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10 Annexes

Biomaterial Collection Form Basic Set, Version 1.1
Information sheet “Collecting a Mid-Stream Urine Specimen”, Version 1.0