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

DZHK-SOP-B-02

Biomaterial Processing Basic Set

Version: V1.1 Valid as of: 15.12.2014

Replaces version: V1.0 dated: 01.09.2014

	Expert Author	**Expert Reviewer**	**Endorsed by Section Head**	**DZHK Approval by CSG**
Name	Tanja Zeller	Nadine Umbach	Matthias Nauck	Andreas Zeiher
Date				
Signature				

Contents

1 List of Abbreviations

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

2 Modifications to Previous Version

Section	Old Version	New Version
6.2	**Processing of blood:** 1. Check the Biomaterial Collection Form and receipt of the primary receptacles 2. Centrifugation of the serum, EDTA, citrate and urine primary receptacles at • 2,000 g für 10 minutes OR 3,000 g for 5 minutes • refrigerated centrifuges: set temperature to 18°C • non-refrigerated centrifuges: allow centrifuge to cool down after each run 3. Aliquot 300-µl portions into corresponding 2D bar-coded aliquot tubes according to rack order (see section 5.2) Document on the Biomaterial Collection Form 4. store locally at -80°C and document the place of storage for future recovery 5. Document sample properties (normal, lipaemic, icteric, haemolytic) on the Biomaterial Collection Form **Processing of urine:** Aliquot into 8 x 300-µl aliquot tubes (FluidX) according to rack order	**Processing in general:** 1. Check the Biomaterial Collection Form and receipt of the primary receptacles 2. Centrifugation of the primary receptacles at 2,000 g for 10 minutes OR 3,000 g for 5 minutes refrigerated centrifuges: set temperature to 18°C non-refrigerated centrifuges: allow centrifuge to cool down after each run 3. Aliquot 300-µl portions into corresponding 2D bar-coded aliquot tubes according to rack order (see section 5.2) 4. Document on the Biomaterial Collection Form store locally at -80°C and document the place of storage for future recovery **Processing of blood:** Document the sample properties (normal, lipaemic, icteric, haemolytic) on the Biomatieral Collection Form **Processing of urine:** Document the sample properties (normal, cloudy, bloody) on the Biomaterial Collection Form
6.2	Graphic illustration	Graphic illustration replaced
Annex	Biomaterial Collection Form Basic Set *(Version 1.0)*	Biomaterial Collection Form Basic Set *(Version 1.0)*

3 Introduction

3.1 Purpose

This standard operating procedure describes the processing and storage of basic sets of biomaterials collected in the context of DZHK projects (normally for a clinical study, a registry or a 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 are 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

The collection, processing and storage of the DZHK basic set of biomaterials (see **Error! Reference source not found.**) are important steps in the pre-analytic process and must be performed in a standardized manner in accordance with the SOPs of the DZHK.

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, a registry and/or a cohort must be stored in a biomaterials bank.

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

	Biomaterial	Aliquot Volume	Aliquot Quantity
Basic Set	Serum	300 µl	10
	EDTA plasma	300 µl	10
	Citrate plasma	300 µl	4
	Urine	300 µl	8
	Buffy coat*	< 300 µl	2

* Freezing of buffy coat for subsequent extraction of DNA

Every aliquot filled (with the exception of the buffy coat) must contain 300 µl. If the amount of biomaterial collected is not sufficient for the intended number of aliquots, then a smaller number of aliquots must be filled.

5 Requirements

5.1 Equipment / Inventory

- centrifuge (refrigerated or non-refrigerated)
- calibrated pipettes
- -80°C freezer with connection to a monitoring system and a failure protection concept

5.2 Special Consumables

- suitable pipette tips
- labelled and rack-mounted aliquot tubes from the basic blood collection set, arranged in the following order:

Positions on the rack:

		1	2	3	4	5	6	7	8	9	10	11	12
Serum	**A**	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		
	B												
EDTA plasma	**C**	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		
	D												
Citrate plasma/buffy coat	**E**	☐	☐	☐	☐					☐	☐		
	F												
Urine	**G**	☐	☐	☐	☐	☐	☐	☐	☐				
	H												

5.3 Materials, Documents and Information Required

- Completed Basic Set Biomaterial Collection Form

6 Workflow

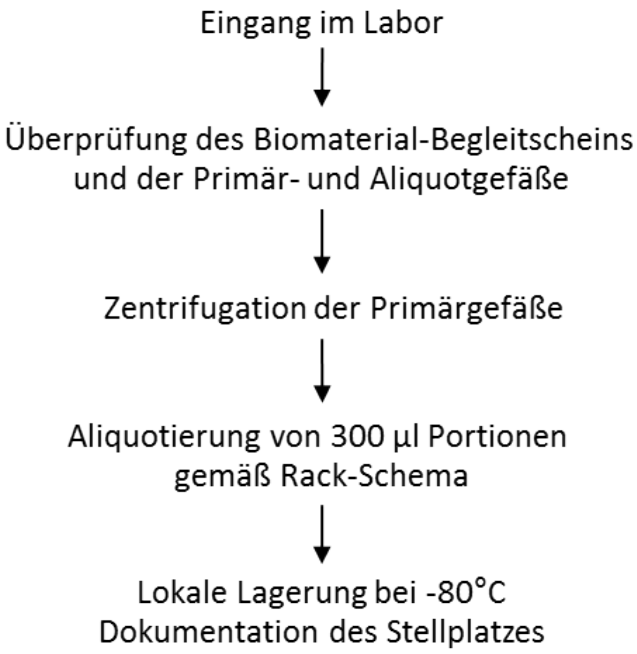
6.1 Specific Requirements

The processing of biomaterials must be carried out in accordance with this SOP by trained personnel. The following standards must be observed:

- Regular disinfection of work surfaces
- Compliance with hygiene regulations

6.2 Flow Chart

Receipt by laboratory – Checking of the Biomaterial Collection Form and the primary receptacles and aliquot tubes – Centrifugation of the primary receptacles – Aliquoting of 300-µl portions according to rack order – Local storage at -80°C, documentation of the storage location



➔ Document each individual step on the Biomaterial Collection Form

Processing in general:

1. Check the Biomaterial Collection Form and receipt of the primary receptacles
2. Centrifuge the primary receptacles at
   - 2,000 g for 10 minutes OR 3,000 g for 5 minutes
   - refrigerated centrifuges: set temperature to 18°C
   - non-refrigerated centrifuges: allow centrifuge to cool down after each run
3. Aliquot 300-µl portions into corresponding 2D bar-coded aliquot tubes according to rack order (see point 5.2)
4. Documentation on the Biomaterial Collection Form
5. Store locally at -80°C and document the storage location for future recovery

Processing of blood:

Document sample properties (normal, lipaemic, icteric, haemolytic) on the Biomaterial Collection Form

Processing of urine:

Document sample properties (normal, cloudy, bloody) on the Biomaterial Collection Form

6.3 Handling Deviations

Deviations from the requirements and workflow described above 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**
DZHK-SOP-B-01	Collection of Biomaterials from Blood and Urine (Version 1.0)

9 List of Contributors

Name	**Function**	**Contribution**
Dr. Tanja Zeller	Head of the Working Group, author of the SOP	Drafted the SOP
Prof. Dr. Matthias Nauck	Head of Scientific Infrastructure	Expert review
Dr. Nadine Umbach	Member of the Working Group, reviewer	Expert review
Christiane Heiß	Member of the Working Group, co-ordinator	
Dr. Jennifer Franke	Member of the Working Group	Expert review
Dr. Christian Geier	Member of the Working Group	Expert review
Sabine Hübler	Member of the Working Group	Expert review
Sophia Lamp	Member of the Working Group	
Antje Müller	Member of the Working Group	Expert review
Dr. Astrid Petersmann	Member of the Working Group	Expert review
PD Dr. Thomas Pickardt	Member of the Working Group	Expert review
Prof. Dr. Daniel Teupser	Member of the Working Group	Expert review
Dr. Christian Troidl	Member of the Working Group	Expert review
Prof. Philipp Wild	Member of the Working Group	Expert review

10 Annex

Biomaterial Collection Form Basic Set, Version 1.1