DZHK
Deutsches Zentrum für
Herz-Kreislauf-Forschung

DZHK-SOP-B-01

Collection of biosamples (DZHK Clinical Study Units)

Version: V2.3 Valid as of: 15.04.2024

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Note: Printouts are not subject to the update process!

Change note: Changes to wording
Notes on underfilling primary vessels
Editorial changes

	Scientific author	Scientific review	Approval WGCR spokesperson	Approval DZHK
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Date				
Signature	**This SOP is a translation from the original German SOP and valid without signatures.**			

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1 Introduction

1.1 List of abbreviations

Abbreviation	Full form
BD	Becton Dickinson AG
DZHK	German Centre for Cardiovascular Research
DZHK-LIMS	laboratory information and management system
EDTA	Ethylene-diamine-tetra-acetic acid
SOP	Standard Operating Procedure

1.2 Objectives

This standard operating procedure is used within the DZHK projects (usually a clinical study, registry or cohort) to describe the process of collecting liquid samples up to transportation to the laboratory (for further processing) under standardized conditions and using the Laboratory Information and Management System (DZHK-LIMS) CentraXX.

Core elements are highlighted in grey in this SOP.

1.3 Background

In scientific studies, various approaches are used to examine human biosamples, such as the determination of (circulating) biomarkers, determination of standard laboratory values, OMICs procedures, DNA/RNA extraction or "biomonitoring", for which a high sample quality is the basis. In order to minimize pre-analytical factors, which have a significant influence on sample quality, the steps of collection, processing and storage must be standardized according to DZHK SOPs. This standardization not only ensures that as many of the above-mentioned techniques as possible can still be carried out after long-term storage of the biosamples, but also enables the comparability of the analytical data obtained from the biosamples processed and stored at the different study centres at a later stage.

1.4 Terms and definitions

Biosamples are e.g. blood, urine, stool and tissue as well as the materials obtained after processing (e.g. plasma, serum, extracted DNA, RNA, stem cells).

DZHK-Biobanking[1] for the DZHK Heart Bank

The DZHK Heart Bank combines valuable resources of biosamples, associated clinical data, image data and genomic data, which are collected within the framework of DZHK projects and other projects. The aim is to make a sustainable contribution to research and the improvement of health. The open resource is available for research projects worldwide. DZHK biobanking is carried out with a firmly defined ***DZHK-set[2]***. The DZHK Heart Bank contains all the DZHK sets gained.

[1] Former „DZHK-Basic-Biobanking “

[2] Former „DZHK-Basic-Set “

Study biobanking[3] to answer the research question

In addition to the DZHK set, a study-specific sample collection according to this SOP may be necessary. The composition of these ***study-sets[4]*** as well as the determination of the collection times is up to the responsible Principle Investigator of the respective DZHK project and will be communicated to the participating study centres and scheduled at the initiation event at the latest.

DZHK-LIMS

The "CentraXX" software is used as the central DZHK LIMS. It is used for process control and documentation of sample collection, processing, storage and retrieval. A defined biosample data set is stored for each biosample. This is then used to automatically determine the quality level of the individual biosamples for subsequent use in further research projects.

2 DZHK-set

A standardized DZHK-set is taken from each participant of a DZHK project **once at the baseline visit (before intervention)**, provided that the participant has consented. The composition of the DZHK set is listed below in Table 1. According to the established clinical routines, either BD or Sarstedt tubes can be used.

Table 1 Type, volume and number of primary vessels

	Primary vessel	BD		Sarstedt	
		volume	number	volume	number
DZHK-set	Serum	10,0 ml	1	7,5 ml	1
	EDTA	10,0 ml	1	7,5 ml	1
	citrate	2,7 ml	1	3,0 ml	1
	urine	11,0 ml	1	10,0 ml	1

3 Requirements for biosample collection and documentation

The following requirements are needed to prepare and follow up the sample collection for the DZHK-set and, if applicable, the study-set:

- user access to the DZHK-LIMS with the user role „Study nurse“
- LIMSPSN (pseudonym for biosample documentation, which can be viewed and printed out by via secuTrial® during registration of participants. The pseudonym consists of a constant prefix and nine digits that vary for each participant, e.g. lims_123456789)
- Hand scanner for scanning the LIMSPSN
- Label printer for printing the labels with identification codes for the primary vessels
- Primary vessels (DZHK-set/Study-set)
- Blood collection set
- Instructions for sterile urine collection for participants (see leaflet "Collection of midstream urine"
- Biosample certificate (optional)

[3] Former „Study-specific biobanking “

[4] Former „Study-specific set “

4 Procedure for biosample collection and documentation

4.1 Specifications

Biosamples are collected in accordance with the locally applicable guidelines. Deviations from the following guidelines do not lead to the exclusion of participants from the study, but are documented as a deviation from the SOP according to the selection list in the DZHK-LIMS.

4.2 Flow chart

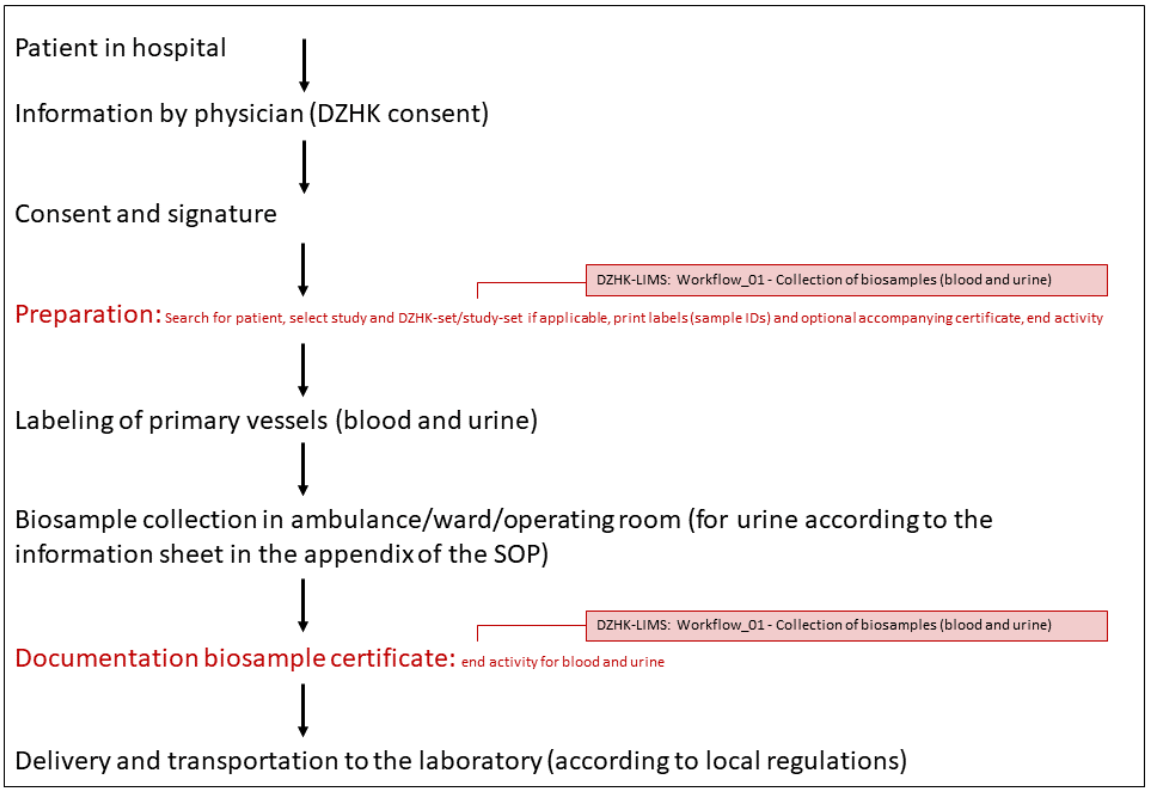

Figure 1: Overview of the procedure for obtaining biosamples and documentation.

4.3 Sample collection procedure and documentation in detail

Blood collection:

- Labelling of all primary vessels with identification codes for blood collection
- Suitable disposal facility for needles, swabs, etc.
- Resting time in unchanged body position before blood collection: 5 minutes
- Collection point on the patient: cubital vein
- Stasis < 1 minute
- Sample sequence for blood collection: serum, citrate, EDTA
- Release of stasis after blood collection has started, i.e. when blood flow into the primary vessel is visible
- No repeated fist closure
- Immediate swivelling even when changing the primary vessels

- Upright storage of the primary vessels in the primary vessel/tube rack
- **NO underfilling** of the primary vessels (if a primary vessel cannot be filled with additive up to the mark, it must be discarded)

Urine collection:

- Labelling of the urine cup **with identification code**
- Information of the participants by means of the information sheet "Collection of midstream urine" (see appendix of this SOP)

Documentation:

- In the DZHK-LIMS CentraXX Workflow 1
- Optional temporary documentation on the printed certificate, then in the DZHK-LIMS (instructions for printing the form in the "Study Nurse - Quick Guide DZHK-LIMS")
- Documentation in the DZHK-LIMS must be completed before the documentation of sample processing (see DZHK-SOP-B-02) can begin

Sample transportation:

- The transport of the primary vessels (if necessary with certificate) to the laboratory for further processing should take place **within 60 minutes** upon sample collection

5 Literature

Guideline of the German Medical Association for Quality Assurance of Laboratory Medical Examinations (German)**.** Deutsches Ärzteblatt | DOI: 10.3238 / arztebl.2019.rili_baek_QS_Labor20192312

6 References to existing DZHK-SOPs

The latest available version is valid.

SOP-ID	**Title**
DZHK-SOP-P-06	Acquisition-IDAT-Informed Consent
DZHK-SOP-B-02	Biosample processing (DZHK Clinical Study Units)

7 Changes

Changes compared to the last version

Section	Description of the change compared to the previous version.
Whole document	Wording former biomaterial becomes biosamples former DZHK basic biobanking becomes DZHK-biobanking former DZHK Basic set becomes DZHK-set former study specific biobanking becomes study biobanking former study specific sample set becomes study-set

4.3	Note on the underfilling of primary vessels
Whole document	Editorial changes

8 Participating persons

Name	**Role**	**Contribution**
Prof. Dr. Tanja Zeller	First author	Draft
Dr. Ivonne Wallrabenstein	Reviewer	Scientific review
Dr. Ilka Wilhelmi	DZHK main office	Coordination

9 Appendix

9.1 Info sheet urine collection

DZHK
Deutsches Zentrum für Herz-Kreislauf-Forschung

Dear participant,

You have consented to participate in a Germany-wide study, a registry or a cohort of the German Center for Cardiovascular Research (DZHK). Your consent includes the collection and processing of urine.
Your urine will be collected to measure various components that can provide information about the function of your kidneys or indicate the presence of diseases.

Please follow these instructions for collecting urine:

1. Please ensure that the urine cup is labelled or marked with your identification code (sticker).
2. Open the urine cup marked with the label without touching the inside of the container or the lid!
3. Only hold the open urine cup in the flow of urine once you have started urinating.
4. If possible, fill the urine cup halfway. Discharge the remaining uncollected urine into the toilet.
5. Close the urine cup without touching the inside of the cup or lid. If necessary, dry the outside of the cup with a paper towel (and disinfectant).
6. Wash your hands.
7. Dispose the closed urine cup according to the instructions given on site.

Thank you!

Infosheet urine collection	As of: 01.12.2023
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