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

DZHK-SOP-K-01

Basic data - Anamnesis/Clinical Diagnoses/physical examination

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Date	26/08/2014	26/08/2014	26/08/2014	26/08/2014
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*This SOP is part of DZHK-SOP-K-02 Anamnesis/Clinical Diagnoses

CONTENTS

1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Full form
ASD	atrial septal defect
COPD	chronic obstructive pulmonary disease
CT	computer tomographie
HDL-cholesterol	High density lipoprotein cholesterol
LDL-cholesterol	Low density lipoprotein cholesterol
MRT	magnetic resonance tomography
pAVK	pheripheral arterial occlusive disease
SOP	standard operating procedure
VSD	ventricular septal defect

1.2 PURPOSE

Uniform definitions are proposed in the context of this SOP when a corresponding risk factor/clinical diagnosis is considered to be present.

1.3 TARGET GROUP

These SOPs are targeted at individuals responsible for entering data into the basic data module “Anamnesis“. These may be e.g. doctors or study nurses.

1.3.1 Inclusion Criteria

Included are all patients who meet the respective inclusion/exclusion criteria of the respective study.

1.3.2 Exclusion Criteria

None. If information cannot be collected in full, it should be collected to the greatest extent possible.

1.4 APPLICATION AND TASKS

The purpose of the anamnesis/clinical diagnoses is to accurately record known cardiovascular risk factors. The anamnesis is a core element of medical diagnostics. The evidence collected during the anamnesis enables a detailed assessment of a patient’s cardiovascular risk.

Collection of the anamnesis/clinical diagnoses is an integral part of all observational and clinical studies of the DZHK.

1.5 TERMS, DEFINITIONS AND EXPLANATIONS FOR THE ECRF MODULE

Date of examination

- is defined as the date on which the examination takes place.

Sex and date of birth

- are defined as the data which appear on the person's identity card.

Height and weight

- Height is measured in the standing position, without shoes and without head covering. Weight is measured in normal street clothing, without a jacket and without shoes. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bed-ridden patients) should one estimate the values or resort to information provided by the proband.

Ethnicity and skin colour

- A person's ethnic origin is defined by their ancestry in relation to a specific ethnic group. This can be determined biologically and/or geographically on the basis of membership of a certain settlement group. Accordingly, a person's skin colour can also be broadly defined. The colour spectrum can be differentiated from light to dark skin colour.

Family history of myocardial infarction or stroke

- is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 55 (when the myocardial infarction/stroke occurred).

Diabetes mellitus

- is defined as diabetes which has been diagnosed and/or treated by a doctor.
  - The American Diabetes Association criteria are:
    - haemoglobin A1c ≥ 6.5 % or a fasting blood glucose level of ≥ 126 mg/dl or a 2-hour blood glucose level of ≥ 200 mg/dl in the oral glucose tolerance test.

Arterial hypertension

- is defined as a current or previous diagnosis of arterial hypertension which was diagnosed and/or is being treated by a doctor. Treatment can consist of e.g. dietary changes, physical activity and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a doctor on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

Dyslipidaemia

- is defined as a current or previous diagnosis of dyslipidaemia which was diagnosed and/or is being treated by a doctor.
- One or more of the following criteria:
  - total cholesterol ≥ 200 mg/dl,
  - LDL cholesterol ≥ 130 mg/dl,
  - HDL cholesterol < 40 mg/dl (men) and < 50 mg/dl (women).

Smoker

- is defined as current or previous use of cigarettes, cigars, pipes or smokeless tobacco.
  "Yes" for daily or occasional smoking (≥ 1x/month);
  "Ex-smoker" for abstinence of more than 6 months; ex-smoker since …;
  "No" for "never smoked".

Current dialysis dependency

- is defined as current regular, at least weekly, renal replacement therapy (including haemodialysis and peritoneal dialysis) within the last 30 days.

Coronary heart disease

- is defined as a current or previous diagnosis by a doctor with one or more of the following criteria:
  - coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
  - prior coronary artery bypass operation,
  - prior percutaneous coronary intervention,
  - arteriosclerosis-induced myocardial infarction.

Status post myocardial infarction

- is a diagnosis of the disease by a doctor. Explanation: Acute myocardial infarction is defined as demonstrated evidence of myocardial necrosis in a clinical setting which is consistent with myocardial infarction.

  One or more of the following criteria must apply:

  - Evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
    - symptoms of ischaemia, angina pectoris,
    - ECG changes indicative of new ischaemia, e.g. ST segment elevations or a new left bundle branch block, development of pathological Q waves in the ECG,
    - imaging studies show a loss of viable myocardial tissue or new regional wall motion abnormalities,

- angiographic evidence of stenosis/blood vessel blockage.

Cardiomyopathy

- is defined as a diagnosis by a doctor of a primary heart muscle disease.

Heart failure

- is defined as a current or previous diagnosis and documentation by a doctor of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, distention of the neck veins, pulmonary oedema on physical examination or pulmonary oedema on chest x-rays. Documentation of reduced left ventricular function alone in the absence of clinical signs of heart failure does not meet the criteria for heart failure.

Atrial fibrillation/flutter

- is defined as a current or previous diagnosis by a doctor of atrial fibrillation or atrial flutter. It is defined as an episode of atrial fibrillation or atrial flutter lasting at least 30 seconds or atrial fibrillation with evidence on the surface ECG or during pacemaker interrogation.

Current or previous medical diagnosis of heart valve disease

- is defined as heart valve disease (incompetence or stenosis), which has been diagnosed and/or treated by a doctor.

Diagnosis by a doctor of a congenital heart defect

- If a patient has a known congenital heart defect, it will be coded here. Congenital heart defects include shunt defects (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life.

Interventional coronary revascularization

- is defined as a percutaneously performed intervention on a coronary artery, e.g. PTCA, stent implantation, rotablation et cetera.

Coronary bypass operation

- is defined as operative myocardial revascularization by means of a bypass graft (e.g. from the internal thoracic artery or using arterial/venous grafts). Where applicable, the date of the most recent operation should be entered.

Heart valve operation

- is defined as a minimally invasive percutaneous (catheter-based) or open surgical procedure on a heart valve.

Implantable cardiac pacemaker or defibrillator

- is defined as status post implantation of a cardiac pacemaker or cardio-verter defibrillator.

CURRENT SECONDARY DIAGNOSES

PAD

- is defined as a current or previous diagnosis by a doctor of peripheral arterial occlusive disease (in the blood vessels of the pelvis and legs, or from the upper extremity of the subclavian artery to the distal extremity). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Possible symptoms are:
  - intermittent claudication,
  - pain at rest,
  - amputation due to severe arterial vascular insufficiency,
  - vascular reconstruction, bypass operation or percutaneous revascularization,
  - a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological $TCPO_2$ measurement, evidence of 50 % or greater stenosis of a peripheral artery by Doppler/duplex sonography, CT, MRT, or angiography).

Stroke/TIA

- is defined as a current or previous diagnosis by a doctor.

Chronic lung disease

- is defined as a diagnosis by a doctor of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals.

Depression

- is defined as a current or previous diagnosis by a doctor. The administration of antidepressants alone does not qualify for a diagnosis of depression.

Cancer more than 5 years ago

- is defined as a current or previous diagnosis of a malignant cancer. Basal cell carcinoma is not counted as a malignancy.

PHYSICAL EXAMINATION

Blood pressure

- The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, tested devices (e.g. Omron 705 IT) should be used for epidemiological trials. Blood pressure measurement begins after the patient has been at rest for at least 5 minutes. Three readings are taken at intervals of 2 minutes; the average values of the second and third readings are entered into the CRF.

Heart rate

- Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after measuring the blood pressure. This should be done manually by counting the radial pulse for 30 seconds; that value multiplied by two should be entered into the CRF (beats/minute).

1.6 Correlations to Other Examinations

Here the correlations between the individual SOPs and other examination procedures are described.

Mandatory preceding examination (SOP …):	*None specified*
Recommended preceding examination (SOP …):	*None specified*
Preceding examination (SOP) to be excluded:	*None specified*
Adverse effects on other parts of the examination:	*None specified*

Mandatory follow-up examination (SOP …):	*None specified*
Recommended follow-up examination (SOP …):	*None specified*
Follow-up examination (SOP) to be excluded:	*None specified*

1.7 Level of Quality

Quality of the data collection method

This SOP describes a data collection method that corresponds to quality level 2 of the DZHK. A higher quality level could possibly be achieved if, for example, standardized interviews such as those used in the German National Cohort were used. Because the studies planned so far in the DZHK do not require a quality level higher than 2, initially only SOPs for that level have been written.

DZHK Quality Levels	
Realisation	
Level 1	The examination is performed in accordance with the guidelines of the medical associations.
Level 2	The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.
Level 3	The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

2 EXAMINATION CONDITIONS

All circumstances are taken into account in order to ensure that the examination is conducted under suitable conditions.

2.1 REQUIREMENTS FOR ROOMS/EQUIPMENT

The examination room should have a room temperature of 22-26 °C. Generally, the room should have a table at which the proband and the interviewer can sit in a comfortable atmosphere in order to conduct the interview.

2.2 EQUIPMENT/HARDWARE

PC with a monitor, keyboard, mouse, printer and printer paper. Depending on the respective study, the forms for standardized documentation of the proband's responses should be available as source files, if needed.

2.3 DOCUMENTS REQUIRED

- Routing slip
- Scan barcode

2.4 INFORMATION REQUIRED

- Examiner number
- Survey number (label)
- Beginning of examination
- Proband number

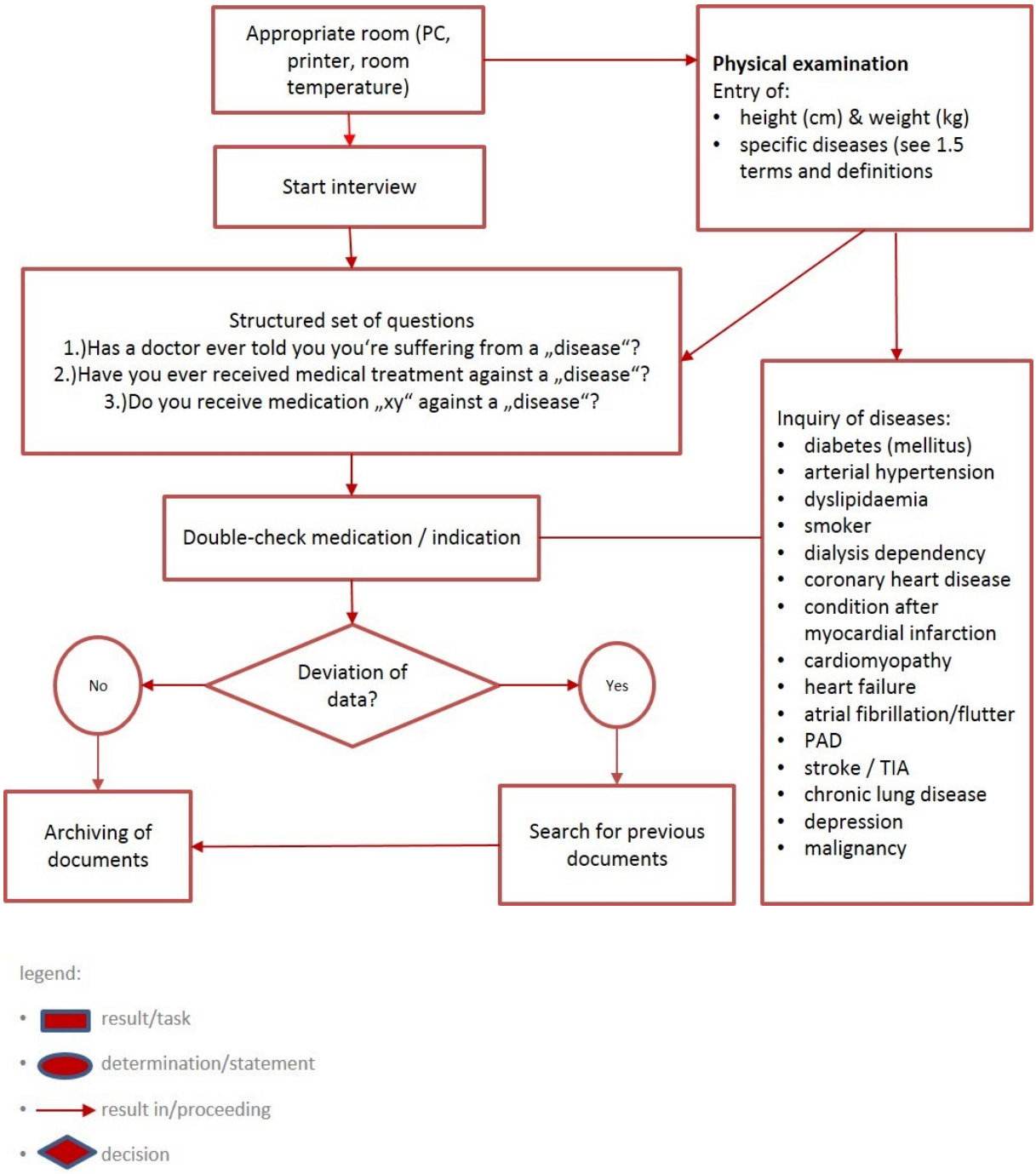
2.5 PERSONNEL

Persons using this SOP must have completed their training in the medical field (e.g. medical assistant, nurse, licensed physician). Students of medicine may use this SOP after they have successfully passed their first medical examination (*Physikum)*.

All users must have completed a prior course of instruction/certification for this SOP or DZHK-SOP-K-02 Anamnesis/Clinical Diagnoses, respectively.

3 IMPLEMENTATION PROCESS/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART



3.2 PREPARING FOR THE EXAMINATION

3.2.1 Preparing the Work Space

Seek out a suitable room with a table. Bring the temperature in the room to between 22 and 26 °C.

3.2.2 Preparing the Equipment

All equipment (PC/laptop/printer) should be switched on and operational. A form (documentation of the source data) should be at hand.

3.3 CARRYING OUT THE EXAMINATION

Physical examination – anthropometry

- Height (in cm) and weight (in kg) are given either as self-reported values (Level 1) or as measured values (Level 2). Whether the values given are based on anamnestic or measured values shall be marked in the CRF.

Anamnesis

A diagnosis is regarded as given if diagnosed by a medical doctor and/or therapy is being administered which is considered to specifically target a certain disease. All documentation in medical documents (e.g. doctor‘s reports) justifies accepting the diagnosis in question as given.

When carrying out the examination, for each clinical diagnosis, the following questions should be asked in the interview:

1. Has a doctor ever told you that you suffer from a “disease”?
2. Have you ever received treatment for a “disease”?
3. Are you taking drug “xy“ for the “disease“?

As a “counter-check“, the interviewer should inquire about and document the indication for each medication the patient is taking. A validation rule will be added to the database which will produce a notification when inconsistencies arise (e.g. negative responses to questions 1-3, but the subject is taking the corresponding medication).

When uncertainties arise (e.g. as to whether the relevant diagnoses have been made, but the subject has consulted doctors for clarification), when and where those consultations took place should be noted as precisely as possible in the remarks field. After the interview, documents of the respective consultancies shall be inquired.

Inquiry about specific diseases, see section 1.5.

3.4 POST-PROCESSING AND REGISTERING THE DATA

A special debriefing session is not planned. The data should be entered without delay (usually within 7 days).

3.5 DEALING WITH DEVIATIONS

If a clear answer cannot be obtained for certain questions, this should be documented.

General particularities should always be noted in the commentary/notes field.

4 LITERATURE AND REFERENCES

ACCF/AHA Guidelines Circulation 2011;124:103-123

5 MODIFICATIONS

Modifications compared with the previous version.

Section	Description of the modification compared with the previous version
….	

6 LIST OF CONTRIBUTORS

Name	Function	Contribution
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7 ENCLOSURES

7.1 eCRF MODULE

Basic Data Set**

General information relating to the anamnesis

I.	Date of recording**	✓ ___ - ___ - ___ tt.mm.jjjj	Kommentar Query
II.	Quality Level**	< Bitte auswählen > ▼	Hilfe Kommentar Query

1. Physical Examination and Socio-demographic Data

1.1.	Sex**	○ male ○ female ○ unknown ○ not assessed	Kommentar Query
1.2.	Date of Birth**	✓ ___ - ___ mm.jjjj	Kommentar Query
1.3.	Height**	✓ ___ cm ○ estimated ○ measured	Kommentar Query
1.4.	Weight**	✓ ___ kg ○ estimated ○ measured	Kommentar Query
1.5.	Ethnicity: Caucasian**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
1.6.	Black skin colour?**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
1.7.	Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 55 for men**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query

2. Cardiovascular risk factors

2.1.	Diabetes mellitus**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
2.2.	Arterial hypertension**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
2.3.	Dyslipidaemia**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
2.4.	Smoker**	○ yes ○ no ○ ex-smoker (stopped ≥ 6 mth. ago) ○ unknown ○ not assessed	Kommentar Query
	Ex-smoker since**	✓ ___ jjjj	
2.5.	Current Dialysis Dependency**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query

3. Cardiac Diagnoses (Anamnesis and Previous Findings)

3.1.	Coronary heart disease**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
3.2.	Status post myocardial infarction**	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query
3.3.	Cardiomyopathy** If the response to this question is "yes", please complete the	○ yes ○ no ○ unknown ○ not assessed	Kommentar Query

	"Cardiomyopathy Diagnostics" form.		
3.4.	**Heart failure****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
3.5.	**Atrial fibrillation/flutter****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
3.6.	**Current or previous diagnosis by a doctor of heart valve disease****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
3.7.	**Diagnosis by a doctor of a congenital heart defect****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
4.	***Previous cardiovascular interventions***		
4.1.	**Interventional coronary revascularization****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
4.2.	**Coronary bypass operation****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
4.3.	**Heart valve operation****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
4.4.	**Implanted pacemaker or defibrillator?****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.	***Current secondary diagnoses***		
5.1.	**PAVK****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.2.	**Stroke/TIA****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.3.	**Chronic lung disease****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.4.	**Depression**** If the response to this question is "yes", please complete the "Depression" form.	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.5.	**Cancer more than 5 years ago****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
5.6.	**Cancer within the last 5 years****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
6.	***The next three anamnestic questions are for women only***		
6.1.	**Menopause?****	◯ yes ◯ no ◯ unknown ◯ not assessed	Kommentar Query
6.1.1.	**Year of menopause****	✓ [ ] jjjj	
6.2.	**Day last menstrual period began****	✓ [ ] - [ ] - [ ] tt.mm.jjjj	
7.	***Blood pressure after 5 minutes at rest***		
7.1.	**Systolic****	✓ [ ] mmHg	Kommentar Query
7.2.	**Diastolic****	✓ [ ] mmHg	
8.	***Heart rate after sitting down for 5 minutes***		
8.1.	**Heart rate****	✓ [ ] per minute	Kommentar Query

10. Laboratory diagnostics (blood)

For clinically stable patients, not more than 1 week old, otherwise up to date!

Kommentar
Query

9.1. Date blood sample was taken**

☑ ____ - ____ - ____ tt.mm.jjjj Where applicable, give date for the oldest value

9.2. Haemoglobin**

☑ ____ , ____

Unit**

- ○ mmol/l
- ○ g/dl

Kommentar
Query

9.3. Creatinine (serum, heparin plasma)**

☑ ____ , ____

Unit**

- ○ µmol/l=nmol/ml
- ○ mg/dl

Kommentar
Query

9.4. Total cholesterol**

☑ ____

Unit**

- ○ mmol/l
- ○ mg/dl

Kommentar
Query

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