SLOVENSKA AKREDITACIJA

S14d5

S14 – ANNEX 5:
SCOPE OF ACCREDITATION OF MEDICAL LABORATORIES

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1 PURPOSE AND GENERAL PROVISIONS

The document provides specific and more concrete provisions as to the way of defining the scope in medical laboratories. General requirements and references applicable to all fields of accreditation are provided in general document S14.

The scope of accredited activities of a medical laboratory shall normally represent the major and essential part of the examinations performed by the laboratory in individual technical field/subfield. The laboratory may start by accrediting a minor part of the activity, which it can later extend to the scope that suits the needs of the users of its services. For all examinations from the scope of accreditation, the laboratory shall provide comprehensive service, including the necessary consultation and interpretation of the results.

The laboratory shall provide the performance of all examinations (including post-examination processes) from the scope of accreditation using the resources (personnel, equipment,…) that are completely under the control of the laboratory, and that fully comply with the rules and procedures of the laboratory's own management system, and by complying with all the requirements of SIST EN ISO 15189, regardless of whether the examinations are being performed at the main site of the laboratory or at other sites.

This document is one of SA's internal regulations, which lay down the requirements for accreditation and the rules of accreditation, of which SA shall maintain public record. Its provisions constitute a part of the Contracts on establishing and maintaining accreditation, which SA concludes with its clients. Valid copies of SA's internal regulations governing the requirements for accreditation and the rules of accreditation shall be available at SA's head office and published on SA's website.

2 TECHNICAL FIELDS

The technical fields of activity of medical laboratories are defined with regard to the main field and the subfield. The names of these fields and subfields are defined in the document D05-11 for those fields for which accreditation procedures have already been introduced. The examination shall be ranged into the field that corresponds to the final result of the examination and the purpose of its use. When a laboratory applying for accreditation is unable to range its activity into any of the defined fields, it shall define in its application the fields as it considers appropriate, while the final definition should be made during the accreditation procedure and added to the list of fields, as appropriate.

3 PRESENTING THE SCOPE OF MEDICAL LABORATORIES

The scope of medical laboratories shall be defined through indication of individual examinations.

When the examinations are conducted in different internal organizational units of the accredited body, the scope shall be presented separately for each unit and for each site, or for a group of units or sites, when a part of the scope is the same for all. The examinations shall be divided into groups according to the technical fields. For each part of the scope, the site shall be defined, e.g. in the laboratory or in the field, or at temporary locations or in a mobile laboratory.

The examination type (parameter or group of parameters to be determined) shall normally be defined by the full name and by the abbreviation, when it is generally accepted. When an exclusively agreed abbreviation is generally used, the examination may exceptionally be designated by the abbreviation only

(e.g. HDL cholesterol). When several different parameters are being determined within the scope of one examination (see examples below), that can differ between laboratories, they must be specified.

The technical principle/method shall be specified in each examination, so that the two details precisely define the principle of the complete examination procedure (see examples below).

The designation and version of the reference document laying down the examination procedure shall be stated. It can be a publicly accessible document or an internal document of the laboratory. Where necessary, limitation to individual parts of the document describing the examination procedure shall be defined. Limitations need to be indicated when other contents are covered by the reference document in addition to the description of this procedure, and/or when the laboratory's accredited activity does not comprise all the examinations or parts thereof defined by the reference document. Individual parts (chapters, points …) of the reference document may be indicated, or some parts may be excluded; and the limitations may also be given descriptively, when necessary. When the examination procedure is laid down in several reference documents, which are not uniquely interrelated, the designations of all those documents (or parts thereof) shall be indicated and connected by the conjunction "and".

Standard CE methods are methods that are performed using CE-labelled measuring equipment (analyzers) and/or diagnostic kits (in compliance with the European regulations governing *in vitro* diagnostic medical devices). When the laboratory uses a CE method, the method shall be defined by stating the equipment rather than the reference document mentioned above; from the equipment, the model of the apparatus and/or the name of the test kit with version identifications must be identified (see examples below). When the laboratory only uses and has verified a part of the examinations/protocols enabled by this equipment, only those shall be stated.

For each examination, the sample types shall also be stated in the forms as received by the laboratory (primary sample). When the laboratory receives samples in different forms or processing stages (e.g. blood, serum, plasma), it may state all the forms or just the form representing the first stage (blood). When the complete group of samples is given (e.g. swabs), it is considered that applicability of the examination and the validity of results is ensured for any sample from the given group/s.

When the laboratory performs collection of primary samples, this shall be stated in the scope of accreditation in connection with the field/subfield of individual examination (or with an individual examination) for which the collection is performed. The sample type, sampling technique and/or method, and the site at which the sampling takes place shall be indicated (see Example 8).

4 PRESENTING FLEXIBLE SCOPES

The additional general rules on accreditation procedure and additional requirements for accreditation in the case of flexible scope of accreditation are laid down in the document S14.

In medical laboratories, flexibility can relate to:

- Introducing modifications (which do not interfere with the techniques and principles) because of a new version/revision of the reference document, or – in the case of standard CE methods – because of introduction of a new version of diagnostic kit or a new analyzer using the same technical principle. The method designation is then presented without stating the version of the equipment (diagnostic kit and/or analyzer) or edition of the document (see Example 2). Major modifications (which interfere with the principles or techniques) shall be addressed as extensions.

- Introducing additional parameters within the framework of a determined examination or group of examinations by using the same analytical system. In that case the examination shall be determined without indicating individual parameters, or the whole group of examinations shall be stated (see Examples 3 and 7).
- Introducing examination for additional sample types by using the same analytical system. The whole group of samples shall be determined within which introduction of additional types is possible.

The laboratory shall publish in the list of accredited activities the actual status of all the data that can be modified within the framework of flexibility of the scope, which by its structure and elements of contents equals the method SA uses for presenting fixed scopes of medical laboratories.

In addition to generally applicable rules for assessing CABs with flexible scope, assessors of medical laboratories shall consider the following specific elements:

- In the case of option to introduce a new version of the method: defining and understanding the criteria as to which modifications can be introduced by the laboratory within the flexibility of scope, and which need to be addressed using the procedure for extension of scope;
- In the case of option to introduce additional parameters: applicability of the defined method for the complete set of parameters within which flexibility is possible;
- In the case of option to introduce additional sample types: applicability of the defined method for the complete set of sample types within which flexibility is possible;
- In all cases: the procedures and rules for validation/verification when introducing methods or their modifications, including unambiguous and correct guidance as to the way and extent of additional validation/verification when introducing individual types of modification of the accredited activity;
- In all cases: the adequateness of presenting the list of accredited activities which shall define all the data in the same way as for the fixed scope of accreditation, these data being based on the results of the validations/verifications performed.

5 EXAMPLES OF SCOPE PRESENTATION

In order to illustrate the above-mentioned rules, the following are some examples of presenting a part of the scope of a medical laboratory's accredited activity.

Example 1

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **klinična biokemija z imunologijo** / *Subfield:* ***clinical biochemistry incl. immunology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	kalcij *calcium*	spektrofotometrija (UV/VIS) *spectrophotometry (UV/VIS)*	kolorimetrična metoda (NM-BAPTA kompleks) *colorimetric method (NM-BAPTA complex)*	Cobas c501(Roche) CA2 Calcium Gen.2 package insert	kri, serum, plazma *blood, serum, plasma*

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **klinična biokemija z imunologijo** / *Subfield:* ***clinical biochemistry incl. immunology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
2.	kalij *potassium*	elektrokemija *electrochemistry*	ion-selektivna elektroda, indirektno (ISE-indirektno) *ion-selective electrode, indirect (ISE-indirect)*	Cobas c311 (Roche) ISE indirect Na, K, Cl for Gen.2 package insert	kri, serum, plazma *blood, serum, plasma*
3.	plinska analiza z oksimetrijo / *blood gas analysis with oximetry*: - pH - pCO_2 - presežek baze / *base excess* - standardni HCO_3^- / *standard bicarbonate* HCO_3^- - dejanski HCO_3^- / *actual* HCO_3^- - saturacija O_2 / O_2 *saturation* - pO_2, - ctO_2, - pO_2(A-a) - ctHb - COHb - metHb - pH (T kor.) / *pH (T corr.)* - pO_2 (T kor.) / pO_2 *(T corr.)* - pO_2(A-a) (T kor.) / pO_2*(A-a) (T corr.)*	elektrokemija, spektrofotometrija (UV/VIS) *electrochemistry, spectrophotometry (UV/VIS)*	elektrode (potenciometrija, amperometrija), spektrofotometrija *electrodes (potentiometry, amperometry), spectrophotometry*	ABL 800 (Radiometer) ABL 800 Reference Manual, 2017	kri *blood*
4.	NSE (Nevron specifična enolaza) *NSE* *(Neuron specific enolase)*	imunokemija *immunochemistry*	elektrokemiluminiscenca (ECLIA) *electrochemiluminiscence (ECLIA)*	Cobas e411 (Roche) Elecsys NSE package insert	kri, serum, plazma *blood, serum, plasma*
5.	oGF (CKD-EPI) (ocena glomerulne filtracije (CKD-EPI)) *eGFR (CKD-EPI)* *(estimated glomerular filtration rate (CKD-EPI))*	izračun *calculation*	izračun oGF po formuli CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) *calculation of eGFR according to formulae CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration)*	Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF, 3rd, Feldman HI, et al., Ann Intern Med. 2009; 150(9):604-12	kri, serum, plazma *blood, serum, plasma*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

Example 2

Tip obsega: **fleksibilni (možnost uvajanja nove verzije metode)**** / *Type of scope:* ***flexible (possibility of introducing new version of the method)*****
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **klinična biokemija z imunologijo** / *Subfield:* ***clinical biochemistry incl. immunology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	kalcij *calcium*	spektrofotometrija (UV/VIS) *spectrophotometry (UV/VIS)*	kolorimetrična metoda *colorimetric method*	Cobas 6000 (Roche)	kri, serum, plazma *blood, serum, plasma*
2.	kalij *potassium*	elektrokemija *electrochemistry*	ion-selektivna elektroda, indirektno (ISE-indirektno) *ion-selective electrode, indirect (ISE-indirect)*	Cobas c311 (Roche)	kri, serum, plazma *blood, serum, plasma*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

**Laboratorij lahko uvede novo verzijo metode (zaradi nove verzije referenčnega dokumenta, diagnostičnega kompleta ali opreme). Podatke o trenutnem stanju obsega vzdržuje laboratorij. */ Laboratory can introduce new version of the method (due to new version of reference document, diagnostic kit or equipment). Details on the actual state of the scope are maintained by the laboratory.*

Example 3

Tip obsega: **fleksibilni (možnost uvajanja nove verzije metode ali dodatnih parametrov)**** / *Type of scope:* ***flexible (possibility of introducing new version of the method or additional parameters)*****
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **klinična biokemija z imunologijo** / *Subfield:* ***clinical biochemistry incl. immunology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	plinska analiza z oksimetrijo / *blood gas analysis with oximetry*	elektrokemija, spektrofotometrija (UV/VIS) *electrochemistry, spectrophotometry (UV/VIS)*	elektrode (potenciometrija, amperometrija), spektrofotometrija *electrodes (potentiometry, amperometry), spectrophotometry*	analizatorji ABL (Radiometer)	kri *blood*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

**Laboratorij lahko uvede novo verzijo metode (zaradi nove verzije referenčnega dokumenta, diagnostičnega kompleta ali opreme) ali dodatne parametre v okviru opredeljene vrste preiskave. Podatke o trenutnem stanju obsega vzdržuje laboratorij. */ Laboratory can introduce new version of the method (due to new version of reference document, diagnostic kit or equipment) or additional parameters within the stated examination type. Details on the actual state of the scope are maintained by the laboratory.*

Example 4

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **laboratorijska hematologija** / *Subfield:* ***laboratory haematology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	hemogram z diferencialno krvno sliko – DKS 5: - levkociti, eritrociti, hemoglobin, hematokrit, MCV, MCH, MCHC, RDW, trombociti, MPV - nevtrofilni granulociti, bazofilci, eozinofilci, limfociti, monociti - retikulociti *blood cell count with differential blood count – DBC 5:* *- leukocytes, erythrocytes, hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, platelets, MPV* *- neutrophilic, basophilic, eosinophilic granulocytes, lymphocytes, monocytes* *- reticulocytes*	pretočna citometrija, določanje števila celic *flow cytometry, cell count*	pretočna citometrija, določanje števila celic s hematološkim analizatorjem *flow cytometry, cell count using haematology analyser*	XT 2000i (Sysmex) Instructions for use, 2007	kri *blood*

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemistry***
Podpodročje: **laboratorijska hematologija** / *Subfield:* ***laboratory haematology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
2.	diferencialna krvna slika (DKS) *blood cell differentiation (DBC)*	mikroskopiranje *microscopy*	mikroskopski pregled krvnega razmaza *microscopic examination of blood smear*	CellaVision, mikroskop *CellaVision, microscope* Cella Vision DM1200, User'Manual, 2017	kri *blood*
3.	PČ (protrombinski čas) *PT (prothrombin time)*	koagulacijski *coagulation*	koagulometrija *coagulometry*	BCS XP (Siemens) Thromborel S, 2016-4.	kri, plazma *blood, plasma*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

Example 5

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **klinična mikrobiologija** / *Field:* ***clinical microbiology***
Podpodročje: **bakteriologija** / *Subfield:* ***bacteriology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	mikroskopski pregled kužnin za določitev kakovosti vzorca in opredelitev morfologije bakterij: gram pozitivne in gram negativne *microscopic examination for general bacteriology purposes and for the determination of the quality of sample, and determination of the properties of bacteria: gram positive/negative*	morfološka karakterizacija mikroorganizmov *morphological analysis of microorganisms*	barvanje po Gramu, svetlobna mikroskopija *Gram staining, light microscopy*	Standards in Microbiological Investigations (SMI) – 1D-1i2, April 2017	telesne tekočine, blato, urin, brisi, kulture *human body fluids, stool, urine, swabs, cultures*
2.	ugotavljanje prisotnosti kolonizacije z večkratno odpornimi bakterijami *determination of colonisation with multiresistant bacteria*	fiziološka in biokemična karakterizacija mikroorganizmov *physiological and biochemical characterisation of microorganisms*	gojenje in izolacija mikroorganizmov z uporabo trdnih in tekočih gojišč, spremljanje rasti *cultivation and isolation of microorganisms using liquid and solid growth media, growth monitoring*	Standards in Microbiological Investigations (SMI) – 1D-1i2, April 2017	blato, urin, punktat, brisi *stool, urine, punctate, swabs*
3.	identifikacija kvasovk *Candida* spp. *identification of yeast Candida spp.*	masna spektrometrija *mass spectrometry*	ionizacija v matriksu z lasersko desorpcijo ter analizo časa potovanja molekul MALDI-TOF *Matrix Assisted Laser Desorption / Ionization-Time of Flight; MALDI-TOF*	interna metoda SOP110, izdaja 3 *in-house method SOP110, version 3*	pozitivna hemokultura, kultura kvasovke *positive haemoculture, yeast culture*
4.	ugotavljanje občutljivosti za antibiotike pri povzročiteljih črevesnih okužb *determination of antibiotic susceptibility with bateria causing gastrointestinal infections*	vrednotenje protimikrobnega delovanja *antimicrobial activity evaluation*	metoda difuzije z diski *disc diffusion method*	EUCAST disk diffusion method, version 9.0, 2019	bakterijske kulture *bacterial cultures*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

Example 6

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **klinična mikrobiologija** / *Field:* ***clinical microbiology***
Podpodročje: **virologija** / *Subfield:* ***virology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	detekcija DNK virusa Epstein Barr *(EBV)* *detection of Epstein Barr (EBV) viral DNA*	verižna reakcija s polimerazo *polymerase chain reaction*	verižna reakcija s polimerazo v realnem času (RT-PCR) z določanjem pražnega cikla *real time polymerase chain reaction (RT-PCR) and determining threshold cycle*	EBV Q – PCR Alert Kit (EliTech) version 4, 2018	kri, likvor, brisi, biopsije *blood, cerebrospinal fluid, swabs, biopsies*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

Example 7

Tip obsega: **fleksibilni (možnost uvajanja dodatnih parametrov)**** / *Type of scope:* ***flexible (possibility of introducing additional parameters)****
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: ***klinična mikrobiologija*** */ Field:* ***clinical microbiology***
Podpodročje: ***bakteriologija, virologija*** */ Subfield:* ***bacteriology, virology***

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	detekcija in/ali identifikacija bakterijskih in virusnih nukleinskih kislin *detection and/or identification of bacterial and viral nucleic acids*	verižna reakcija s polimerazo *polymerase chain reaction*	pomnoževanje nukleinskih kislin v realnem času (RT-PCR) z določanjem pražnega cikla *real time polymerase chain reaction (RT-PCR) and determining threshold cycle*	*GeneXpert® IV*	blato *faeces*

*Če je metoda standardna CE metoda, je opredeljena z navedbo modela opreme in/ali reagenčnega kompleta, sicer pa z oznako referenčnega dokumenta, v katerem je metoda opisana. / *If the method is a standard CE method, it is defined by the equipment model and/or test kit, otherwise the reference document where the method is described is identified.*

**Laboratorij lahko uvede dodatne parametre v okviru opredeljene vrste preiskave. Podatke o trenutnem stanju obsega vzdržuje laboratorij. / *Laboratory can introduce additional parameters within the stated examination type. Details on the actual state of the scope are maintained by the laboratory.*

Example 8

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemisty***
Podpodročje: **-** / *Subfield:* **-**

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
1.	odvzem primarnega vzorca za biokemijske preiskave *collection of primary sample for biochemical examinations*	venepunkcija *phlebotomy*	postopek z zaprtim sistemom *procedure with closed system*	Joint EFLM-COLABIOCLI Recommendation for venous blood sampling 1.1, June 2018, Clin Chem Lab Med 2018;56(12):2015-2038.	venska kri *venous blood*

Tip obsega: **fiksni** / *Type of scope:* ***fixed***
Mesto izvajanja: **v laboratoriju** / *Site:* ***in the laboratory***
Področje: **medicinska biokemija** / *Field:* ***medical biochemisty***
Podpodročje: **-** / *Subfield:* **-**

Št. ***No.***	**Vrsta preiskave** ***Examination type***	**Tehnični princip** ***Technical principle***	**Metoda(-e)** ***Method(-s)***	**Oznaka*** ***Identification****	**Vrste vzorcev** ***Sample types***
2.	odvzem primarnega vzorca za biokemijske preiskave *collection of primary sample for biochemical examinations*	punkcija kože *skin puncture*	-	Priporočeni postopek za odvzem kapilarne krvi, *Recommendation for capillary blood sampling* SZKKLM, 2020.	kapilarna kri capillary blood

6 CHANGES WITH REGARD TO PREVIOUS REVISION

The rules and examples for determination of the activity of collecting primary samples have been changed. The changes are marked.

7 TRANSITORY AND FINAL PROVISIONS

For accredited laboratories, the transition of the stated primary sample collection activities in the Annexes to the Accreditation Certificates shall be carried out no later than upon decision after the next regular assessment from the entry into force of this edition.

8 CONTROL OF THE DOCUMENT

The document is adopted by the SA Board after its content has been considered and adopted by the Accreditation Committee. If the SA Board disagrees with the proposal which was approved by the Accreditation Committee, it shall be referred back to the Accreditation Committee for consideration. Changes that do not affect the content can be adopted by the SA Board without the involvement of the Accreditation Committee.

A valid copy of this document shall be located in i4 (SA's information system). A clean copy shall be published on SA's website, and available in printed form at SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies hereof shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on SA's website.