

MEDICAL BIOCHEMISTRY LABORATORIES AS PART HEALTH CARE SYSTEM IN SERBIA



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Center for Medical Biochemistry, Clinical Centre of Serbia

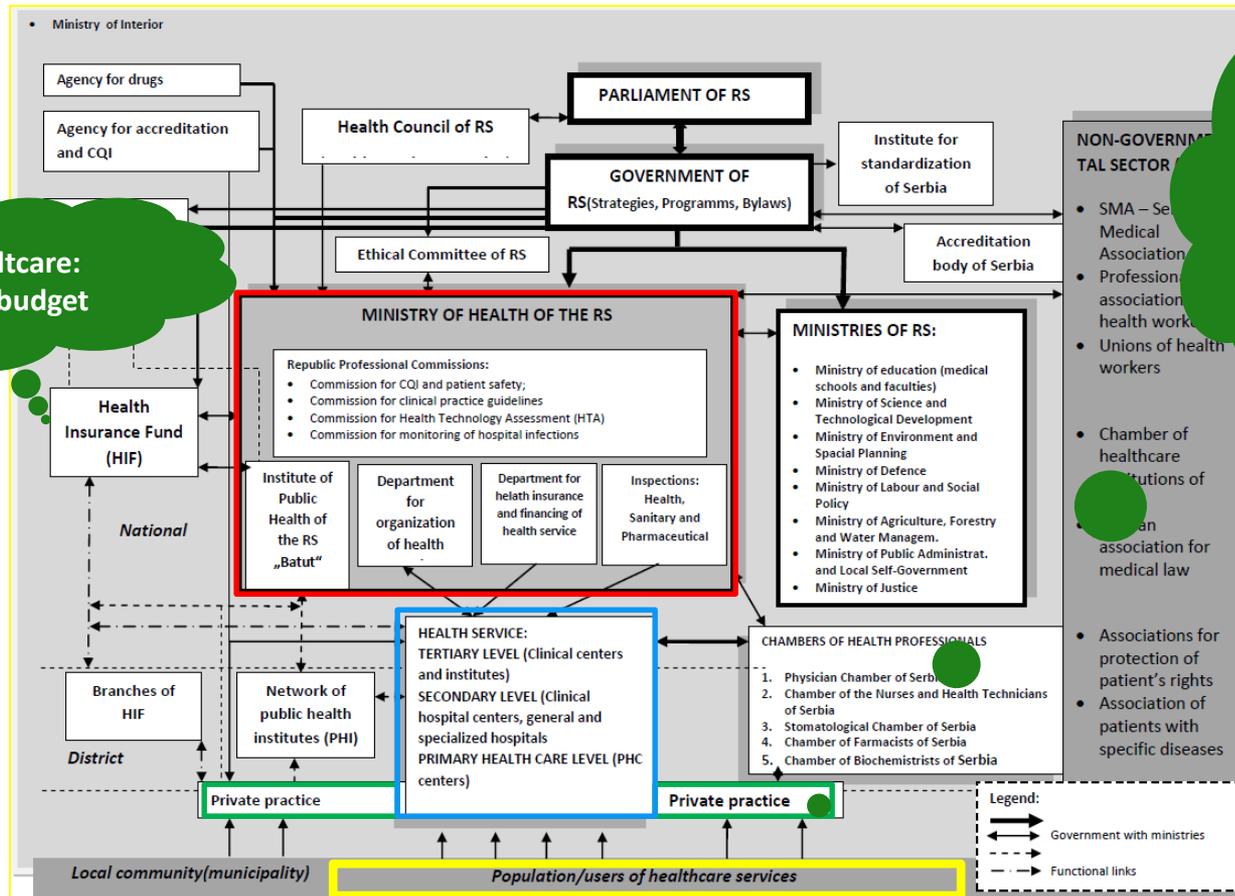


Overview

- ❑ **Health care organization in Serbia**
- ❑ **Medical biochemistry laboratory diagnostics in Serbia**
- ❑ **Education and postgraduate training of MB**
- ❑ **Profession of MB/CB in Serbia**
- ❑ **DMBS (SMBS)**

Health Care Organization in Serbia

Health care in Serbia is provided through a wide network of public health care institutions owned and controlled by the Ministry of Health.



Funding of healthcare: contribution + budget

38% of expenditure for healthcare services in Serbia are paid out of pocket

Serbian healthcare system provide easy access to comprehensive health services for all population.

Medical Biochemistry in Serbia

Medical biochemistry is the usual name for clinical biochemistry or clinical chemistry in Serbia

- Medical biochemistry in Serbia is **the largest sub-discipline of laboratory medicine**
- It includes all aspects of clinical chemistry, laboratory hematology with coagulation, immunochemistry, and laboratory endocrinology.



Medical Biochemistry Laboratory Diagnostics in Serbia

- Is performed in an appropriate scope according to the level of healthcare (primary, secondary, tertiary) as regulated by the Nomenclature of Laboratory Services

I - NOMENCLATURE OF LABORATORY SERVICES - JOINT GENERAL LABORATORY ANALYSIS

II - NOMENCLATURE OF LABORATORY SERVICES - GENERAL CHEMATOLOGICAL ANALYSIS AND CHEMISTRY ANALYSIS

III - NOMENCLATURE OF LABORATORY SERVICES - BIOCHEMICAL AND IMMUNOCHEMICAL ANALYZES

IV - NOMENCLATURE OF LABORATORY SERVICES - IMMUNOLOGICAL ANALYSIS

V - NOMENCLATURE OF LABORATORY SERVICES - IMUNOHEMATOLOGICAL ANALYSIS

VI - NOMENCLATURE OF LABORATORY SERVICES - MICROBIOLOGICAL ANALYSIS

VII - NOMENCLATURE OF LABORATORY SERVICES - TOXICOLOGICAL ANALYSIS

VIII - NOMENCLATURE OF LABORATORY SERVICES - CYTOGENETICS AND MOLECULAR GENETICS ANALYSIS

IX - NOMENCLATURE OF LABORATORY SERVICES - TISSUE TYPES ANALYSIS

X - NOMENCLATURE OF LABORATORY SERVICES - PATHOHYSTHOLOGICAL ANALYSIS

На основу члана 55. став 1. Закона о здравственом осигурању („Службени гласник РС”, бр. 107/05, 109/05 – исправка, 57/11, 110/12 – УС, 119/12, 99/14, 123/14, 126/14 – УС, 106/15 и 10/16 – др. закон),

Министар здравља доноси

ПРАВИЛНИК

о Номенклатури лабораторијских здравствених услуга на примарном, секундарном и терцијарном нивоу здравствене заштите

“Службени гласник РС”, бр. 34 од 4. маја 2018, 104 од 28. децембра 2018.

Члан 1.

Овим правилником утврђује се Номенклатура лабораторијских здравствених услуга на примарном, секундарном и терцијарном нивоу здравствене заштите.

Номенклатура из става 1. овог члана одштампана је уз овај правилник и чини његов саставни део.

Члан 2

Medical Biochemistry Laboratories in Serbia

According to the number and complexity of the tests performed as well as to the qualifications of the personnel in the medical biochemistry laboratories are:

- General (in a primary health care setting)
- Special (in an community or country hospital)
- Subspecial (in a special hospital or clinical hospital)
- Clinical (in a University clinical hospital)



Medical Biochemistry Laboratories in Serbia



Clinical Centre of Serbia



Klinički centar Vojvodine

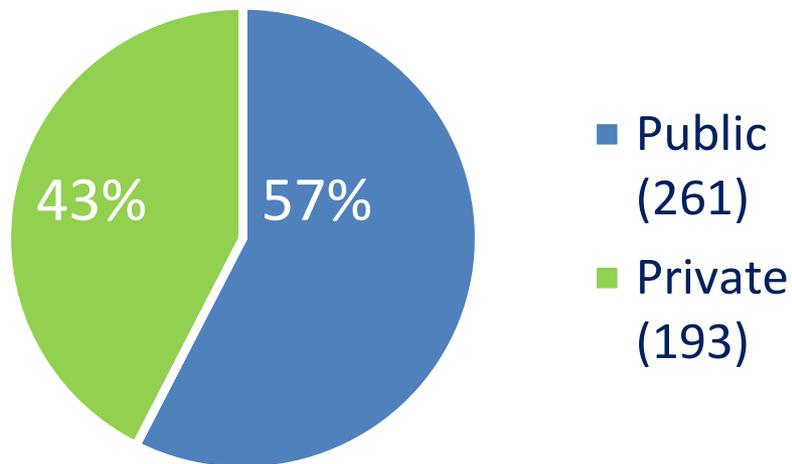


Clinical medical biochemistry laboratories as a part of the University hospitals are a teaching units for undergraduate and postgraduate education of medical biochemists.



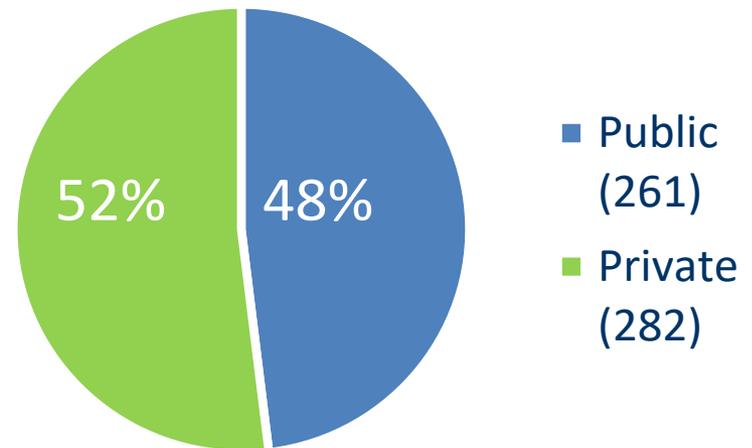
Medical Biochemistry Laboratories in Serbia

June 2015



Total number of Laboratories 454

April 2019



Total number of Laboratories 543

Private Medical Biochemistry Laboratories



ZAVOD ZA LABORATORIJSKU DIJAGNOSTIKU
KONZILIJUM



bio-lab
laboratorije



Private laboratories are either general or special laboratories

NEOLAB
POLIKLINIKA ZA LABORATORIJSKU
DIJAGNOSTIKU



M MEDIGROUP
LABORATORIJA 0-24
preko
850
analiza



ZDRAVSTVENA USTANOVA
JUGOLAB[®]
ZAVOD ZA LABORATORIJSKU DIJAGNOSTIKU



Service of Medical Laboratories in Serbia

- The activities of the laboratory service are clearly defined:
 - adequately qualified staff
 - appropriate space
 - equipment meets all the requirements
 - LIS in the function of efficient delivery of laboratory services
 - quality of work and the safety of patients, etc.

Education of Medical Biochemists in Serbia

- In 1987 at the Faculty of Pharmacy in Belgrade a **five years undergraduate** branch was established, educating Medical Biochemists under a special program.
- Since school-year 2006/2007 the new **program according to Bologna declaration** has been established .
- The program is designed for candidates who plan to pursue a career in medical biochemistry laboratories within the Health Care System or a career in pure and applied medical biochemistry research and education.

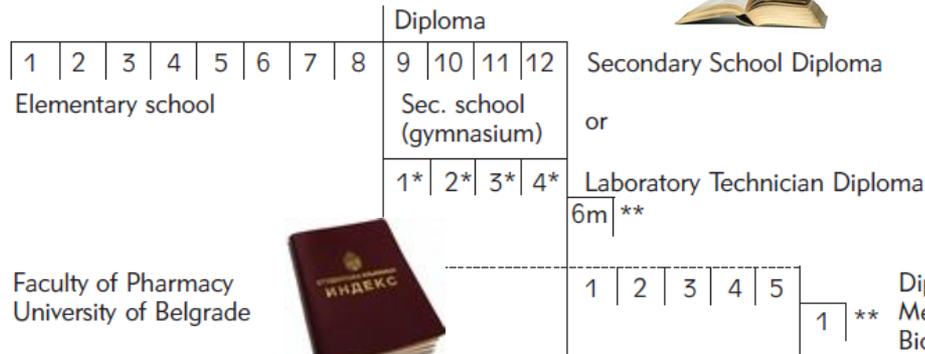


Education of Medical Biochemists in Serbia

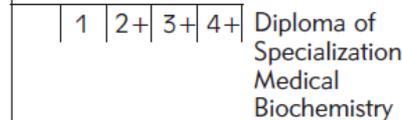
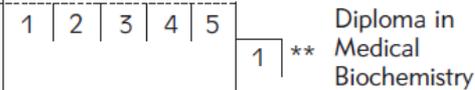
- Creative work and research in medical biochemistry requires broad formal training in basic natural sciences and medicine and extensive laboratory experience.



Educational Outline of Medical Biochemist at University of Belgrade - Faculty of Pharmacy

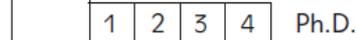


Faculty of Pharmacy
University of Belgrade



Note:

- * = practical work experience.
- ** = post-diploma practical work experience at hospitals required for obtaining license.
- + = organized practical work, supervised work in specialized biochemical laboratories.



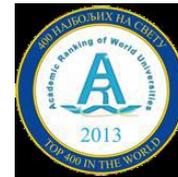
and



- # Subspecialization: Clinical Enzymology, Clinical Immunochemistry and Laboratory Endocrinology
- ## Specialist Academic Studies, Biochemical Diagnostics

The Health Care Specialization Studies of Medical Biochemists

- **Department of Medical Biochemistry** at University of Belgrade – Faculty of Pharmacy organizes the specialization studies in medical biochemistry
- **Schools of Medicine** at University of Belgrade, University of Niš and University of Novi Sad organize the specialization studies in clinical biochemistry



The Health Care Specialization Studies at University of Belgrade-Faculty of Pharmacy

Since school-year 2006/2007 the new postgraduate program of **four-year specialization** according to EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine has been established #.

Specialization in medical biochemistry takes four years, and is divided into two stages:

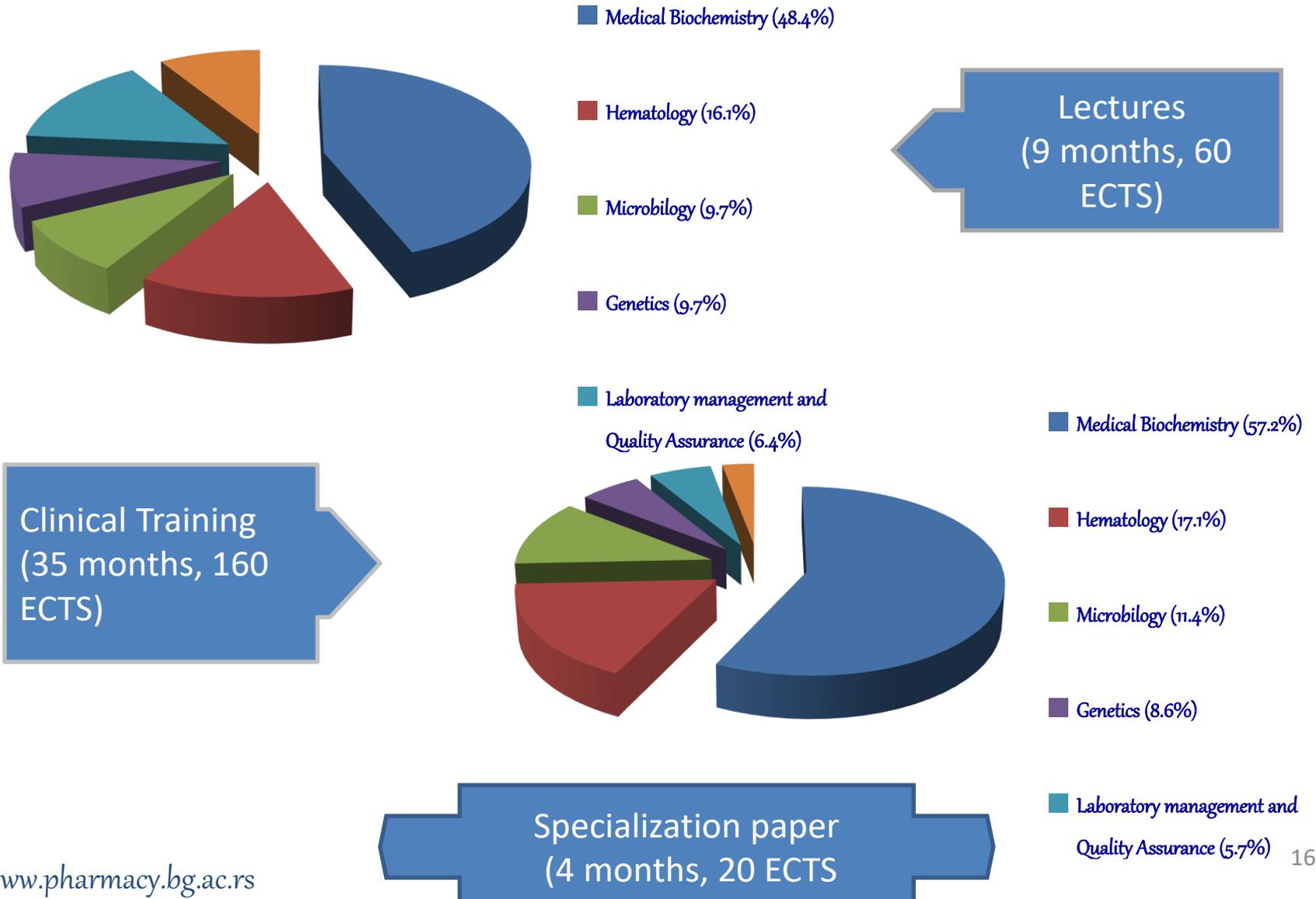
Year 1: The subjects in the first year of postgraduate scientific study of medical biochemistry are accepted as the **theoretical part** of the specialization;

Years 2–4: Comprise **residency**, mainly in Departments of Laboratory Diagnostics in University Hospitals and partly in specialized biomedical laboratories in general or specialized hospitals



Simone Zerah et. al. Clin Chem Lab Med 2008; 44(1): 110-120

The Health Care Specialization Studies (48 months, 240 ECTS)



European Register of Specialists in Laboratory Medicine

The logo for the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) consists of the letters 'EFLM' in a stylized, blue, sans-serif font. The letter 'M' has a small orange dot at its bottom right corner.

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE



SOCIETY OF MEDICAL BIOCHEMISTS OF SERBIA

Memorandum of Understanding

between EFLM and DMBS for automatic registration of individuals on the European Register of Specialists in Laboratory Medicine

This document has been prepared to define a collaborative working relationship between the European Federation of Laboratory Medicine (hereinafter referred to as EFLM) (AISBL, Coudenberg 70, 1000 Bruxelles, Belgium) and the “Serbian Society of Medical Biochemists of Serbia (DMBS)” (hereinafter referred to as National Society) (Vojislava Ilića 94b, I sprat, stan 7, 11050 Beograd-Voždovac, Serbia) for the automatic registration of National Society Members in the **European Register of Specialists in Laboratory Medicine** (hereinafter referred to as “EuSpLM Register”) and to define the responsibilities of each part.

European Register of Specialists in Laboratory Medicine

AISBL - REGISTERED OFFICE
Coudenberg 70 - 1000 Brussels (BE)
(registration number: 0524.835.227)

EFLM OPERATIVE OFFICE
Via C. Farini 81 - 20159 Milano (IT)
Tel: +39-3895320051 - efm@eflm.eu
www.eflm.eu

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EFLM is a Regional Federation of the
International Federation of Clinical Chemistry
and Laboratory Medicine (IFCC)

EFLM

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

November 29th 2018

To: Professor Majkic-Singh
Director, Society of Medical Biochemists of Serbia

Dear Professor Majkic-Singh

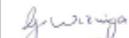
The EFLM Register of Specialists in Laboratory Medicine (EuSpLM)

Thank you for submitting Serbia's application for recognition of Equivalence in knowledge, skills and competence with colleagues across Europe. I am delighted to advise that the application was successful and the Society of Medical Biochemists of Serbia is now eligible to establish automatic registration with effect from 1st January 2019.

To achieve auto-registration an agreement has to be signed between EFLM and SMBS (in attachment the proposed agreement). After the signature, the list of the names of individuals who meet the approved Equivalence of Standards should be submitted (on the attached excel template) to Silvia Cattaneo at the EFLM Office (silvia.cattaneo@eflm.eu). On registration your society will receive an annual invoice of 10 Euros per registrant. Please note that it is then the Serbian society's on-going responsibility to ensure that only individuals able to meet the approved Equivalence of Standards are captured on the annual list that is submitted to the database. In practice therefore some people will come off the list each year (eg retirement or not participating in CPD) and some new people will hopefully be added. For good governance the Registrar is expected to conduct random audits.

Once again, can I take the opportunity to thank you for Serbia's support for the Register! Your society's members will be the first non-European Union members to join and, as you know, the Register is key to setting high quality, equivalent standards of practice and helps promote laboratory medicine's profile.

Yours sincerely,


G. Wieringa
Chair, EFLM Profession Committee

Cc: Ivana Rako, EFLM Register Registrar, EFLM Profession Committee
Inez Anne Haagen, Chair, EFLM WG: Register, EFLM Profession Committee

Your society's members will be the first non-European Union members to join and, as you know, the Register is key to setting high quality, equivalent standards of practice and helps promote laboratory medicine's profile.

<https://www.dmbj.org.rs/>

Requirements for Practicing Medical Biochemistry in the Health Care System in Serbia

Medical biochemistry laboratories in Serbia and medical biochemists as a profession are part of the Health Care System and their activities are regulated through:

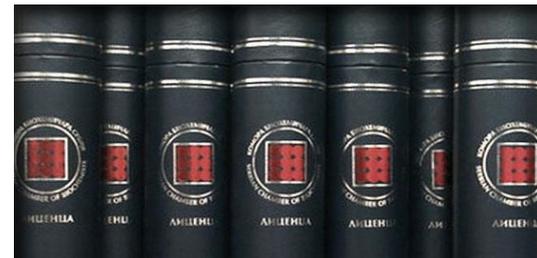
- ✓ **The Health Care Law** and
- ✓ The Rules issued by the **Serbian Chamber of Biochemists**





The Serbian Chamber of Biochemists

- It was founded as an **independent, professional organization** whose purpose is to promote the conditions necessary for performing duties required by the professions of pharmacy graduates – M. Sc. in Medical Biochemistry, pharmacy graduates – Medical Biochemistry Specialists, and medical doctors – Clinical and Medical Biochemistry Specialists.
- The **License** of medical biochemists will be renewed every **7 years** on the basis of successful completion of continuing education requirements during that period.

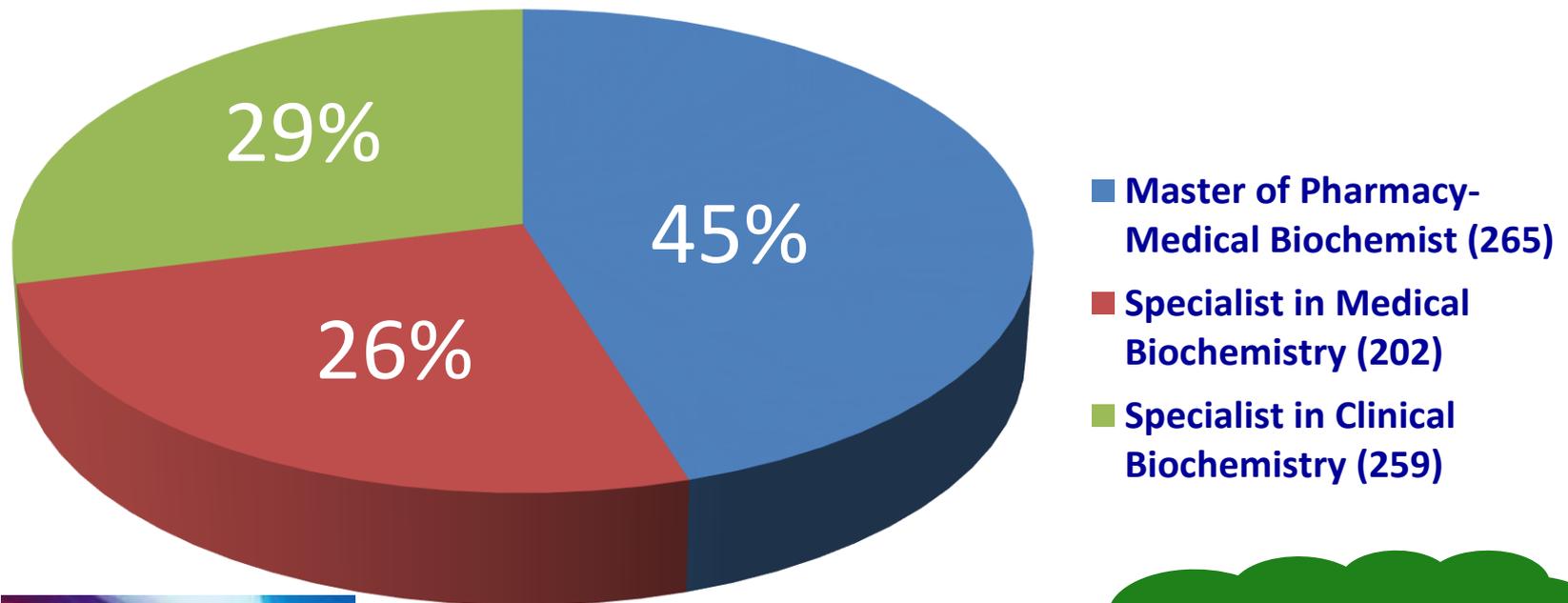


Requirements for Practicing Medical Biochemistry in the Health Care System in Serbia

- ❖ The licensing for medical biochemistry professionals was begun after the establishment of the Health Council in 2009 and license renewal depends on having collected a minimum number of points for accredited Continuous Medical Education activities.
- ❖ Educational programs have been accredited by the Health Council.
- ❖ Minimum requirement for renewal of the license is **20 credits per year** gathered from different types of the programs (courses, symposiums, congresses, publications, etc.)



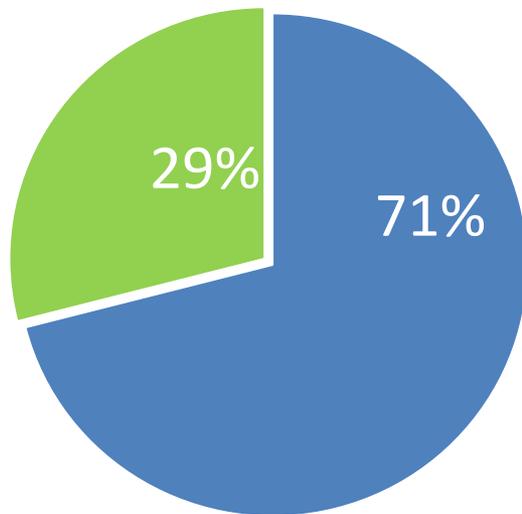
Structure of Members of the Serbian Chamber of Biochemists 2019



Total = 1089

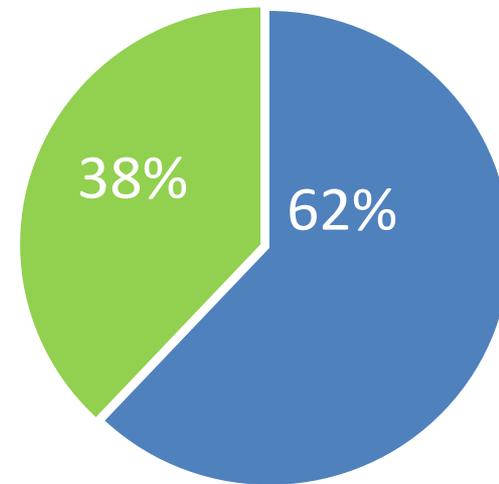


Percent of Medical Biochemists with Licence in Medical Biochemistry Laboratories in Serbia



June 2015

■ Public
■ Private



April 2019

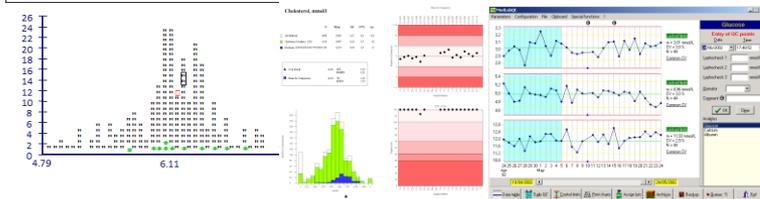
Responsibilities of Medical Biochemists

Specialist of medical biochemistry is responsible for complete laboratory organization and management from pre- to post-analytical phase, laboratory protocol preparation, internal and external quality control, laboratory accreditation etc.



SNEQAS
Serbian National External Quality Assessment

Kontrola: DMBJ-27 Datum određivanja: 18/5/1998 Datum izvođenja: 15/6/1998 Sifra laboratorije: 44
Parametar: HOLESTEROL Jedinica: mmol/L
Vaša metoda: A holesterol-oksidaza



Accreditation of Medical Biochemistry Laboratories in Serbia

- Accreditation is not mandatory.
- The Accreditation Body of Serbia (ATS) as the national accreditation body in Serbia offer an ISO 15189 and ISO 17025 accreditation for medical biochemistry laboratories.
- ATS has accredited 25 medical biochemistry laboratories, 11 as competent according to SRPS ISO 15189 and 5 according to SRPS ISO 17025.

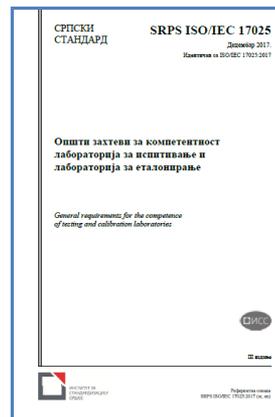


АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ ► ACCREDITATION BODY OF SERBIA

Accreditation according to SRPS EN ISO 15189:2014 and SRPS ISO TEC 17025:2017



25
laboratories



5
laboratories

Accreditation of Healthcare Institutions in Serbia

- In the process of accreditation of healthcare institutions by the Agency for Accreditation of Health Institutions in Serbia (AZUS), an independent public agency, one of the requirements for accreditation is the assessment of the work of laboratory service.
- AZUS was founded in October 2008 and for the design of the Serbian accreditation system International Society for Quality in Health Care standards were adopted as the benchmark.
- **AZUS accredited 212 healthcare institutions.**



AGENCY FOR ACCREDITATION OF
HEALTH CARE INSTITUTIONS OF SERBIA





Society of Medical Biochemists of Serbia

SMBS established in 1955 has accomplished significant activities in the field of education of clinical chemists through the organization of:

- Congresses (biennial),
- Biochemical days (every year)
- Innovations in laboratory medicine (every year)
- Congresses of Balkan Clinical Laboratory Federation,
- Scientific Conference “Professor Ivan Berkes” (every year)
- EFCC/EFLM Symposium for Balkan Region
- Educational seminars, etc.



After more than half a century of fruitful work, the SMBS continues to be the leader and support for clinical laboratory professionals in Serbia.



Journal of Medical Biochemistry

- The SMBS publishes the Journal of Medical Biochemistry, the official journal of the Society of Medical Biochemists of Serbia with international peer-review.
- The Journal publishes original scientific and specialized articles on all aspects of clinical chemistry, medical biochemistry and the related scientific disciplines where chemistry, biochemistry, molecular biology and immunochemistry are dealing with the study of normal and pathologic processes in human beings.
- The Journal is published four times a year and its 2017 impact factor is 1.378 (<http://www.degruyter.com/view/j/jomb>).



