Essential and additional strategies to achieve and maintain quality in genetic laboratories: insights from a high-throughput diagnostic laboratory

Poliklinika Breyer

Laboratoriji za medicinsku biokemiju, mikrobiologiju i citologiju

University of Zagreb Faculty of Science Department of Biology

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Lucija Belužić, May 2024, Zagreb

Introduction / Why quality matters?

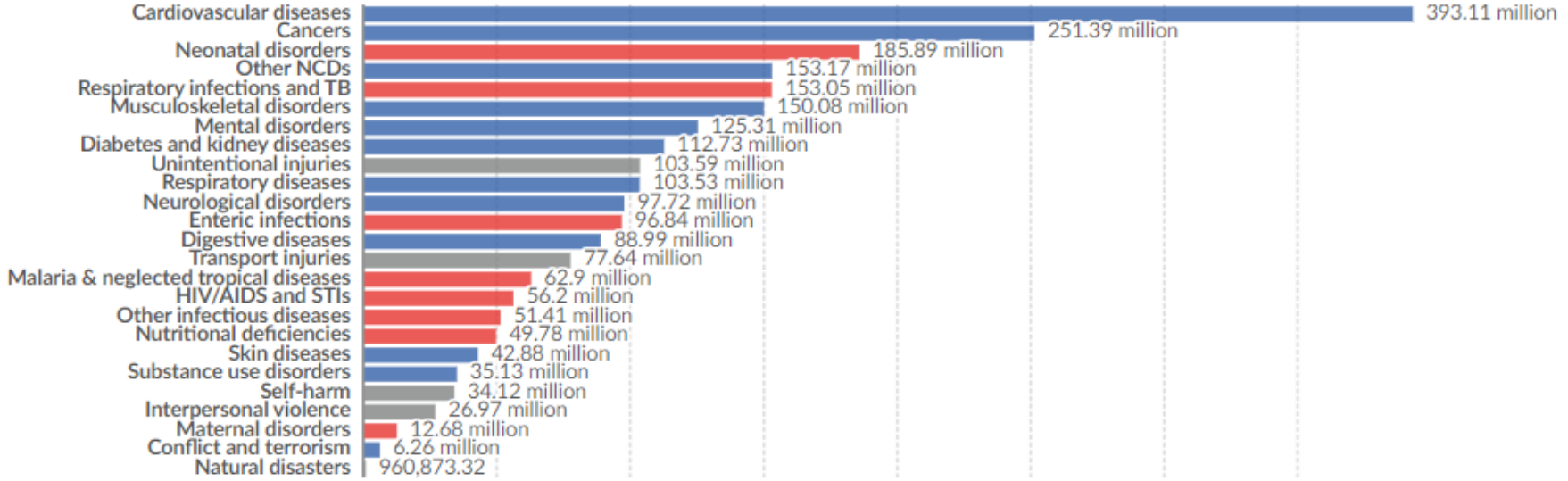
Burden of disease by cause, World, 2019

Our World in Data

Total disease burden, measured in Disability-Adjusted Life Years (DALYs) by sub-category of disease or injury.
DALYs measure the total burden of disease – both from years of life lost due to premature death and years lived with a disability. One DALY equals one lost year of healthy life.

Table | Chart

Change country or region



1990 — 2019

Data source: IHME, Global Burden of Disease (2019) – Learn more about this data

Note: Non-communicable diseases are shown in blue; communicable, maternal, neonatal and nutritional diseases in red; injuries in grey.

OurWorldInData.org/burden-of-disease | CC BY

Introduction / Why quality matters?

Polyclinic Breyer
- 4 locations
- Medical biochemistry laboratories
- Microbiology department
- Genetics department
- Citology and pathology department
- Radiology

Genetics department

Next generation sequencing >75 000 reports in 5 years
Molecular genetics laboratory (qPCR and genotyping)
Karyotyping
Computer assisted semen analysis
Genetic counseling
Laboratory services for partners

MBL akreditiran prema normi

HRN EN ISO 15189

LABORATORY BIOSAFETY MANUAL
FOURTH EDITION
AND
ASSOCIATED MONOGRAPHS

LABORATORY DESIGN AND MAINTENANCE

World Health Organization

MINISTARSTVO ZDRAVLJA

1709

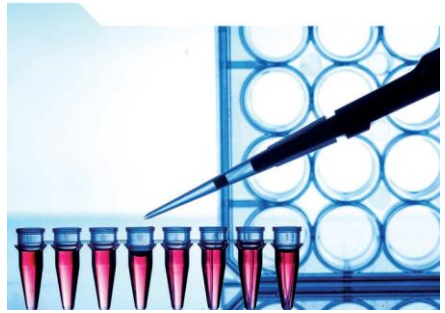
Na temelju članka 10. Zakona o lijekovima (»Narodne novine«, broj 71/07, 45/09 i 124/11), ministar zdravlja donosi

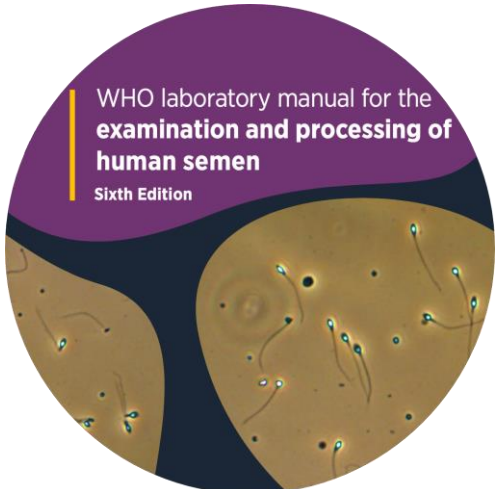
PRAVILNIK

O DOBROJ LABORATORIJSKOJ PRAKSI

OECD Series on Testing and Assessment

Guidance Document on Good In Vitro Method Practices (GIVIMP)





Examples of Breyer laboratories

Low	Medium	High
1-20 / week	50 - 150 samples /week	>400 samples / week
Cell culture, microscopy	qPCR	Next generation sequencing
Karyotyping / Semen analysis	Microbiology, genotyping	Non inasive prenatal testing
Manual	Semi-automated	Fully automated
Specially trained staff in one variable shift	Medium number of staff in one to two shifts	Many employees in two to three shifts
Years long education (low number of analyses, special skillset)	Education slower (lower number of samples, but various analyses)	Education fast (a lot of runs)