

# Switzerland: History and Context

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- ▶ May 1992 Federal Constitution, Art. 119  
Reproductive medicine and gene technology involving human beings
  - ▶ 119f “the genetic material of a person may be analysed, registered or made public **only with the consent of the person concerned** or if the law so provides”
- ▶ 1993 Swiss Academy of Medical Sciences
  - ▶ Directives médico-éthiques concernant les examens génétiques sur l'homme
- ▶ Oviedo Convention
  - ▶ Signed 1999; ratified 2008; entry into force 1.11.2008.
- ▶ **Swiss federal Law on Human Genetic Testing 2004**
  - ▶ Entry into force 1.4.2008





## Loi fédérale sur l'analyse génétique humaine (LAGH)

810.12

du 8 octobre 2004 (Etat le 1<sup>er</sup> av

**Bundesgesetz  
über genetische U  
(GUMG)**

vom 8. Oktober 2004 (S

*English is not an official language of the Swiss Confederation. This translation is provided for information purposes only and has no legal force.*

## Federal Law on Human Genetic Testing (LHGT)

of 8 October 2004 (Status as of 1 April 2007)

## Legge federale sugli esami genetici sull'essere umano (LEGU)

dell'8 ottobre 2004 (Stato 1° aprile 2007)

DE: GUMG  
FR: LAGH  
IT: LEGU  
ENG (no legal  
force)

[http://www.admin.ch/ch/d/sr/c810\\_12.html](http://www.admin.ch/ch/d/sr/c810_12.html)  
[http://www.admin.ch/ch/f/rs/c810\\_12.html](http://www.admin.ch/ch/f/rs/c810_12.html)  
[http://www.admin.ch/ch/i/rs/c810\\_12.html](http://www.admin.ch/ch/i/rs/c810_12.html)  
Google: federal LHGT



## Article 2: Purpose

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- ▶ This law aims:
  - a. to protect human dignity and personality;
  - b. to prevent improper genetic testing and the improper use of genetic data;
  - c. to ensure the quality of genetic tests and the way their results are interpreted.

### **Article 4**      Non-discrimination

No one may be discriminated against on grounds of his or her genetic material.



## Applications

- ▶ stipulates the conditions under which human genetic testing may be performed:
  - ▶ a. in the medical context;
  - ▶ b. in the context of employment;
  - ▶ c. in the context of insurance;
  - ▶ d. in the context of liability.
- ▶ Also the creation of DNA profiles for the purpose of determining the filiation or identity
- ▶ does not apply to genetic testing performed for research purposes.

## Definitions

- ▶ genetic tests:
  - ▶ cytogenetic and molecular genetic tests
  - ▶ to determine hereditary characteristics of human genetic material [...]
  - ▶ and **all** other laboratory tests whose **immediate purpose** is to provide such information about genetic material.
- ▶ molecular genetic tests:
  - ▶ tests to determine the molecular structure of nucleic acids (DNA and RNA)
  - ▶ and the immediate gene product.



# Prescription, counselling and consent

Diagnostic		Prenatal	"Family planning"	Pre-symptomatic
Prescription	by medical doctors who are authorised to practice their profession independently or under the supervision of such	by doctors who have received appropriate postgraduate training		
Informed consent	Genetic and prenatal testing [...] may not be performed unless the person [...] has given his or her voluntary consent  <i>Written consent is not required.</i>	Consent [...] must be obtained in writing.		
Genetic counselling	Genetic and prenatal testing [...] may not be performed unless the person concerned has been provided with adequate information about the testing ...	Must be preceded and followed by non-directive genetic counselling provided by a qualified person. The counselling session must be documented. A « sufficient » period of time must be allowed between the counselling and the test. <i>The required topics for counselling are detailed (Art. 14.3, 15, 16).</i>		



# Other aspects of the LHGT

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- ▶ Sample reuse
- ▶ Disclosure of data
- ▶ Self-testing (IVDD)
- ▶ Penal considerations
- ▶ Creation of the Expert Commission (ECHGT, GUMEK)
- ▶ Direct-to-consumer testing : see [www.bag.admin.ch/gumek](http://www.bag.admin.ch/gumek) or Google echgt gumek)
- ▶ Insurance providers
  - ▶ may not require either presymptomatic or prenatal genetic tests prior to providing insurance.
  - ▶ may neither require the disclosure of, nor utilize, results of prior presymptomatic or prenatal genetic tests or tests for family planning purposes
- ▶ Key exceptions:
  - ▶ Life insurance >400'000 CHF
  - ▶ Invalidity > 40'000 CHF
- ▶ Employment
  - ▶ Only in exceptional cases, with consent
- ▶ Liability
  - ▶ Only in exceptional cases
- ▶ Filiation etc
  - ▶ Outside the context of administrative proceedings, DNA profiling to determine filiation may be performed only with the written consent of the persons concerned



# Legal setting for genetic testing

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## Law

Counselling & consent

Right to prescribe

Right to perform

## Ordinance

Authorization

Laboratory requirements

**ISO  
15189/17025**

## LAMal

Reimbursement

EQA

Right to bill



# Federal Analysis List (annex to Law on Health Insurance, LAMal)

## ► Positive list:

- Diagnostic tests which are obligatorily reimbursed by (private) health insurance

## ► Diseases

## ► Techniques

## ► Tariffs

## ► Authorized specialization

Rev.	No. pos.	TP	Dénomination (Analyses de génétique moléculaire)	domaine de laboratoire
	2315.03	185	Déficit de l'alpha 1-antitrypsine  Limitation: au maximum 3 fois par échantillon primaire, non cumulable avec 2910.00 supplément pour détermination complexe de génétique moléculaire	G
	2315.04	185	Déficit de l'alpha-galactosidase (M. Fabry)	G
	2315.05	185	Déficit de la bêta-glucosidase (M. Gaucher)	G
	2315.06	185	Mucoviscidose	G
	2315.07	185	Diabète insipide	G
	2315.08	185	Intolérance au fructose	G
	2315.09	185	Galactosémie	G
	2315.10	185	Malabsorption du glucose-galactose	G
	2315.11	185	Déficit de la glycérol-kinase	G
	2315.12	185	Glycogénoses	G
	2315.13	185	Hémochromatose, familiale (HFE): recherche des mutations p.C282Y et p.H63D  Limitation: au maximum 2 fois par échantillon primaire, non cumulable avec 2115.13 Hémochromatose, 2910.00 supplément pour détermination complexe de génétique moléculaire	CGH



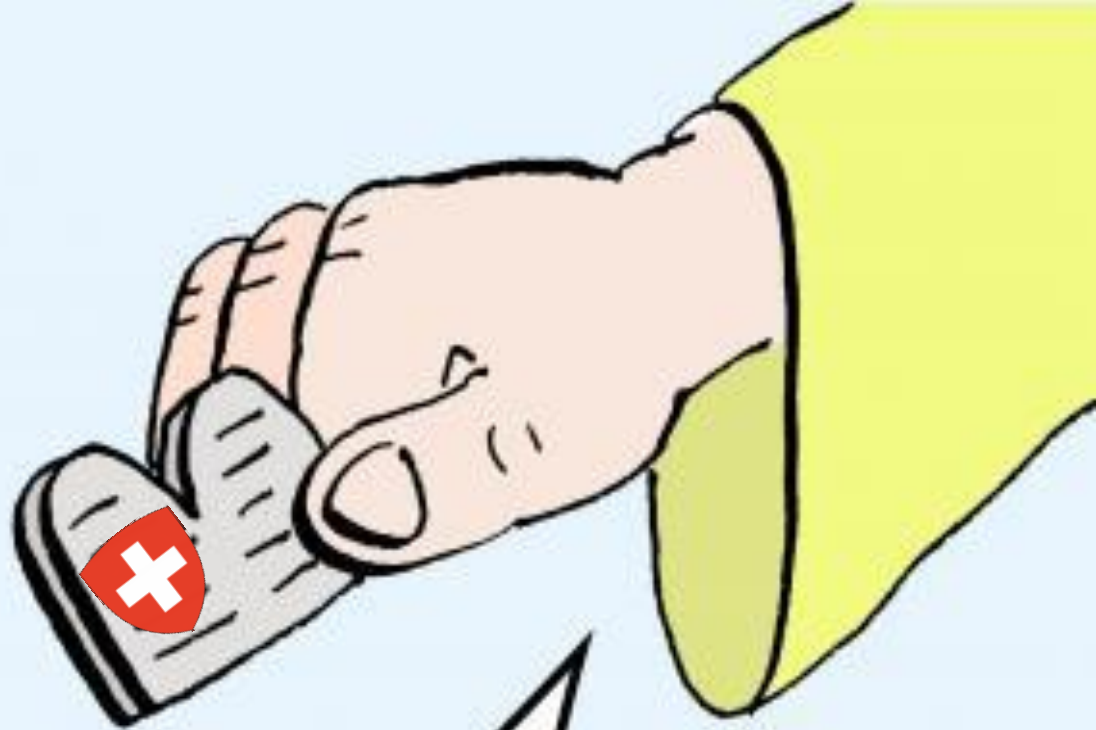


## Positives

- ▶ The Law exists
- ▶ It is still possible to practice medical genetics!
- ▶ Theoretical protection against discrimination
- ▶ Protection against testing by labs without competence
- ▶ Authorization encourages EQA and accreditation

## Negatives

- ▶ The reimbursement of tests is highly discriminatory
  - ▶ The Analysis List defining reimbursement is unprofessional, full of absurdities, and potentially open to abuse
- ▶ Accreditation is not formally required
  - ▶ The criteria for authorization are poorly defined and not enforced
  - ▶ Examples: EQA, professional titles, quality management



**HERE YOU GO -  
DON'T SAY I DIDN'T  
WARN YOU.**