



Regulation of professions in the field of

Laboratory testing

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Introduction

Under the Agreement on the Free Movement of Persons (AFMP)¹, professionals from the EU/EFTA can have their qualifications recognised if the professional activity for which they are qualified in their country of origin is regulated in Switzerland.

This document aims to describe the Swiss regulations in the sector concerned. Regulated professional activities are those that are subject to specific training requirements and where access to the profession in question is only possible for professionals holding a specific qualification that is defined in relation to the Swiss education system. Foreign professionals may only access a regulated profession once their qualifications have been recognised.

If holders of foreign professional qualifications wish to pursue a professional activity other than the ones described in this document, they are free to do so without obtaining recognition of their qualifications (non-regulated professional activity). In this case, it is the labour market that will dictate their chances of finding employment or, in the case of self-employed persons, of securing contracts.

Information pertaining to the process for **offering services** (as opposed to permanent establishment in Switzerland) are described at the end of this document.

¹ Agreement of 21 June 1999 between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons, SR 0.142.112.681.

1 Regulated activities and different types of authorisation

Activities in the field of laboratory testing are regulated by federal law for the most part. Regulated activities and types of authorisation² are set out in the following:

- Human Genetic Testing Act (HGTA)³
- Human Genetic Testing Ordinance (HGTO)⁴
- Epidemics Act (EpidA)⁵
- Microbiology Laboratories Ordinance⁶
- Health Insurance Act (HIA)⁷
- Health Insurance Ordinance (HIO)⁸
- FDHA Ordinance on Compulsory Health Insurance Benefits (HIBO)⁹
- Ordinance on DNA Profiling for Civilian and Administrative Purposes (DNAPO)¹⁰
- DNA Profiles Act¹¹
- DNA Profiles Ordinance¹²
- FDJP Ordinance on DNA Testing Laboratory Requirements¹³

It should be noted that the AFMP does not mention any postgraduate qualifications in laboratory medicine for Switzerland, which is why there is no automatic recognition of qualifications in this field (see Article 21 ff. of Directive 2005/36/EC). Instead, the general system of recognition defined in Art. 10 to 15 of the Directive applies.

In the equivalence recognition procedure, postgraduate training in laboratory medicine is compared in each case with [FAMH postgraduate training](#) (information available in German and French), which is mandatory for all medical laboratory specialists in Switzerland. The reference documents used to assess candidate dossiers are as follows:

- [Postgraduate training regulation and programme for medical laboratory specialists FAMH](#)
- Catalogue of training objectives ([Annex II](#) of FAMH Regulation)
- [Training record](#)

The recognition procedure is described in the [FOAG Criteria](#) document dated 15 March 2023 (in German). These criteria and other information can be found on the FOPH Website in the section entitled, '[Laboratorien und Laborleiter](#)' ('Laboratories and Laboratory Managers', available in German, French and Italian)

For information regarding recognition procedures for other qualifications and a list of the competent authorities, see Section 3.

² Laboratories carrying out activities in the area of human genetics, microbiology and DNA profiling must obtain a federal licence or recognition. In other areas of laboratory medicine, cantonal requirements on operating or professional licences must be taken into account.

³ Federal Act of 15 June 2018 on Human Genetic Testing (HGTA; SR 810.12).

⁴ Ordinance of 23 September 2022 on the Genetic Testing of Human Beings (HGTO; SR 810.122.1), see in particular Art. 12 and 13 and Art. 44.

⁵ Federal Act of 28 September 2012 on Combating Communicable Human Diseases (Epidemics Act, EpidA; SR 818.101), see in particular Art. 16.

⁶ Ordinance of 29 April 2015 on Microbiology Laboratories (SR 818.101.32), see in particular Art. 4-8.

⁷ Federal Act of 18 March 1994 on Health Insurance (HIA; SR 832.10), see Art. 35 para. 2 und 36a.

⁸ Ordinance of 27 June 1995 on Health Insurance (HIO; SR 832.102), see in particular Art. 53-54a.

⁹ FDHA Ordinance of 29 September 1995 on Compulsory Health Insurance Benefits (HIBO; SR 832.112.31), see in particular Art. 42f.

¹⁰ Ordinance of 14 February 2007 on DNA Profiling for Civilian and Administrative Purposes (DNAPO; SR 810.122.2), see in particular Art. 6.

¹¹ Federal Act of 20 June 2003 on the Use of DNA Profiles in Criminal Proceedings and for the Identification of Unknown and Missing Persons (DNA Profiles Act; SR 363).

¹² Ordinance of 3 December 2004 on the Use of DNA Profiles in Criminal Proceedings and for the Identification of Unknown and Missing Persons (DNA Profiles Ordinance; SR 363.1), see in particular Art. 2.

¹³ Ordinance of the FDJP of 8 October 2014 on Performance and Quality Requirements for Forensic DNA Testing Laboratories (FDJP Ordinance on DNA Testing Laboratory Requirements; SR 363.11).

2 Types of activity and training required

The training required varies according to the type of testing performed and the professional's position in the laboratory (Laboratory manager – Section 2.1, or Laboratory staff – Section 2.2).

2.1 Laboratory manager

TESTING TYPE	REQUIRED QUALIFICATION	COMPETENT AUTHORITY FOR RECOGNITION OF FOREIGN QUALIFICATIONS ¹⁴
Human genetics¹⁵		
Cytogenetic¹⁶ and molecular genetic¹⁷ testing for medical purposes¹⁸	FAMH -certified specialist in laboratory medicine or equivalent qualification indicating the title of the corresponding testing technique ¹⁹	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
	Pathologist, specialist in molecular pathology or equivalent qualification ²⁰	Medical Professions Commission (MEBEKO), Postgraduate Training Section²¹
		Federal Office of Public Health (FOPH), Health Protection Directorate²²
	For cytogenetic or molecular analyses of gametes or embryos <i>in vitro</i> in a medically assisted reproduction method as defined in Art. 5a of the Federal Act of 18 December 1998 on Medically Assisted Reproduction (MAR), the laboratory manager must hold the qualification FAMH specialist in medical genetic analysis or FAMH	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate

¹⁴ Depending on the qualification required, different authorities are responsible for recognition. Workplace training and/or work experience or professional competence are assessed by the relevant authority responsible for authorisation or recognition.

¹⁵ Laboratories that wish to carry out cytogenetic or molecular genetic testing for medical purposes require authorisation from the Federal Office of Public Health (FOPH), Health Protection Directorate. Information and forms can be found here: www.bag.admin.ch/genetische-laboratorien.

¹⁶ Tests conducted in order to establish the number and structure of chromosomes (Art. 3 let. b HGTA).

¹⁷ Tests conducted in order to determine the molecular structure of nucleic acids (DNA and RNA) and the immediate gene product (Art. 3 let. c HGTA).

¹⁸ Genetic testing that has a medical purpose or provides information about genetic diseases and disorders and/or the risk of being affected by such a disease (see Art. 19 in connection with Art. 3 let. d–i HGTA). There are no qualification requirements for the management of laboratories that carry out genetic testing for non-hereditary markers linked to cancer diseases or the management of laboratories that carry out genetic testing associated with blood transfusions and transplants (see Art. 2 para. 1 and 2 HGTA).

¹⁹ Qualification referred to in Art. 12 para. 1 let. a–e HGTO and Art. 42 para. 3 and 43 HIO: FAMH-certified specialist in medical genetics, clinical chemistry, haematology or clinical immunology. The Federal Office of Public Health (FOPH) decides whether a foreign qualification referred to in Art. 12 para. 1 and Art. 42 para. 3 and 43 KLV is equivalent to a comparable Swiss qualification (Art. 12 para. 4 HGTO and Art. 54a para. 1 HIO). Recognition of equivalence with a pluridisciplinary qualification is no longer possible.

²⁰ The Federal Office of Public Health (FOPH) decides whether a foreign qualification referred to in Art. 12 para. 1 let. f HGTO is equivalent to a comparable Swiss qualification (Art. 12 para. 4 HGTO).

²¹ MEBEKO: responsible for recognition of foreign postgraduate qualifications covered by the Medical Professions Act (e.g. pathology specialist).

²² Information regarding recognition of foreign postgraduate qualifications in molecular pathology can be obtained from the Federal Office of Public Health (FOPH), Health Protection Directorate - Biomedicine Division - Biosafety, Human Genetics and Reproductive Medicine Section, 3003 Bern, geneticstesting@bag.admin.ch.

	specialist in laboratory medicine, medical genetics, or equivalent qualification ²³	
Cytogenetic and molecular genetic testing for non-medical purposes ²⁴	FAMH -certified specialist in laboratory medicine or equivalent qualification ²⁵	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
	Pathologist, specialised in molecular pathology or equivalent qualification ²⁶	Medical Professions Commission (MEBEKO), Postgraduate Training Section ²⁷
		Federal Office of Public Health (FOPH), Health Protection Directorate ²⁸
	Degree from a cantonal university or university of applied sciences in biology, chemistry, biomedicine, pharmaceutical sciences or life sciences or other qualification recognised as equivalent as well as proof of at least one year of work experience in a molecular biology laboratory and knowledge of human genetics ²⁹	There is no need to obtain recognition of the foreign qualification in these instances as these activities are not listed as regulated professional activities in Directive 2005/36/EC. However, swissuniversities may provide guidance on assessment/confirmation of academic level , if this is helpful. ³⁰
	University degree in human medicine, dental medicine, veterinary medicine or pharmacy or other qualification recognised as equivalent as well as proof of at least one year of work experience in a molecular biology laboratory and knowledge of human genetics ³¹	Medical Professions Commission (MEBEKO), Undergraduate Training Section ³²

²³ The Federal Office of Public Health (FOPH) decides whether a foreign qualification referred to in Art. 12 para. 1 let. a HGTO is equivalent to a comparable Swiss qualification (Art. 12 para. 4 HGTO).

²⁴ Genetic testing for non-medical purposes aimed at clarifying particularly sensitive personality traits, namely genetic testing for lifestyle, individual characteristics and genealogical research (Art. 31 para. 1 HGTA, Art. 37-39 HGTO).

²⁵ FAMH specialist in medical genetics, clinical chemistry, haematology or clinical immunology (see Art. 44 para. 1 HGTO). The Federal Office of Public Health (FOPH) decides whether a foreign postgraduate qualification referred to in Art. 12 para. 1 HGTO is equivalent to a comparable Swiss qualification (Art. 12 para. 4 HGTO).

²⁶ The Federal Office of Public Health (FOPH) decides whether a foreign qualification referred to in Art. 12 para. 1 let. f HGTO is equivalent to a comparable Swiss qualification (Art. 12 para. 4 HGTO).

²⁷ MEBEKO: responsible for recognition of foreign postgraduate qualifications covered by the Medical Professions Act (e.g. pathology specialist).

²⁸ Information regarding recognition of foreign postgraduate qualifications in molecular pathology can be obtained from the Federal Office of Public Health (FOPH), Health Protection Directorate - Biomedicine Division - Biosafety, Human Genetics and Reproductive Medicine Section, 3003 Bern, geneticstesting@bag.admin.ch.
Art. 44 HGTO.

²⁹ Art. 44 HGTO.
³⁰ As part of the authorisation process, the Federal Office of Public Health (FOPH) must be provided with a corresponding level certificate/assessment.

³¹ Art. 44 HGTO

³² MEBEKO: responsible for recognition of foreign postgraduate qualifications covered by the Medical Professions Act.

Microbiology ³³		
Diagnostic³⁴ or epidemiological³⁵ testing	FAMH -certified specialist in laboratory medicine or equivalent qualification ³⁶ indicating the title of the corresponding type of testing	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
Testing to rule out communicable diseases³⁷	FAMH -certified specialist in laboratory medicine or equivalent qualification indicating the title of the corresponding type of testing ³⁸	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
	Haematology specialist qualification as stipulated in MedPA ³⁹ or equivalent qualification and proof of the professional competence needed to conduct this type of testing and interpret the results ⁴⁰	Medical Professions Commission (MEBEKO), Postgraduate Training Section ⁴¹
Testing of samples taken from the environment⁴²	FAMH -certified specialist in laboratory medicine or equivalent qualification indicating the title of the corresponding type of testing ⁴³	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
	University degree in microbiology and proof of the professional competence needed to conduct this type of testing and interpret the results University degree in chemistry, biochemistry, or biology and proof of the professional competence needed to conduct this type of testing and interpret the results⁴⁴	Recognition of the foreign qualification is not required in this case as the activities in question are not listed as regulated professional activities in Directive 2005/36/EC. However, swissuniversities may provide guidance on <u>assessment/confirmation of academic level</u> , if this is helpful.

- ³³ Facilities that conduct or wish to conduct microbiological tests to detect or rule out communicable diseases must obtain a licence from the Swiss Agency for Therapeutic Products (Swissmedic). The required certificates are examined as part of the authorisation procedure. Information and forms can be found here: [Microbiology laboratories](#).
- ³⁴ Laboratory tests for the detection of a communicable disease in a specific patient (Art. 3 let. a of the Microbiology Laboratory Ordinance; SR 818.101.32).
- ³⁵ Laboratory tests for the early detection and monitoring of a communicable disease in the population, and for the prevention and control of that disease (Art. 3 let. b of the Microbiology Laboratory Ordinance; SR 818.101.32).
- ³⁶ Art. 5 of the Microbiology Laboratory Ordinance and Art. 42 para. 3 HIBO. The FOPH decides on recognition of equivalence of foreign postgraduate qualifications in the field of laboratory medicine (Art. 54a para. 1 HIO).
- ³⁷ Laboratory tests to rule out, during screening, the presence of a pathogen specific to a communicable disease in blood, blood products or transplants (Art. 3 let. c of the Microbiology Laboratory Ordinance; SR 818.101.32).
- ³⁸ Art. 6 let. a and c of the Microbiology Laboratory Ordinance; SR 818.101.32. The FOPH decides on recognition of equivalence of foreign postgraduate qualifications in the field of laboratory medicine (Art. 54a para. 1 HIO).
- ³⁹ Medical Professions Act of 23. June 2006 (MedPA, SR. 811.11)
- ⁴⁰ Art. 6 let. b and c of the Microbiology Laboratory Ordinance; SR 818.101.32. Professionals must be able to demonstrate that they have worked with these systems and technologies and are able to interpret the results.
- ⁴¹ MEBEKO: responsible for recognition of foreign postgraduate qualifications covered by the Medical Professions Act (e.g. haematology specialist).
- ⁴² Laboratory tests to detect a human pathogen in samples taken from the environment following a repeated natural occurrence or intentional, unintentional or presumed release of a pathogenic organism likely to cause significant harm (Art. 3 let. d and e of the Microbiology Laboratory Ordinance; SR 818.101.32).
- ⁴³ Art. 7 let. a and d of the Microbiology Laboratory Ordinance; SR 818.101.32.
- ⁴⁴ Art. 7 let. b and d of the Microbiology Laboratory Ordinance; SR 818.101.32. The professional must be able to demonstrate both technical skills and specialist skills relating to high-risk pathogens.

	University degree in human medicine, dental medicine, veterinary medicine or pharmacy, together with two years of work experience in microbiological testing and proof of the professional competence needed to conduct this type of testing and interpret the results ⁴⁵	Medical Professions Commission (MEBEKO), Undergraduate Training Section ⁴⁶
Other areas of laboratory medicine ⁴⁷		
Haematology, clinical chemistry, clinical immunology testing	FAMH -certified specialist in laboratory medicine or equivalent qualification indicating the title of the corresponding testing technique ⁴⁸	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate
DNA profiling ⁴⁹		
Creation of DNA profiles for civilian and administrative purposes ⁵⁰		
<i>Samples taken directly from the person concerned</i> ⁵¹	- FAMH-certified specialist in laboratory medicine - Other qualification attesting to the requisite knowledge of human genetics for parentage certificates and identifications⁵² Note: at least two years of practical experience in the area of human genealogical parentage reporting, including at least 100 parentage reports prepared independently⁵³	Federal Office of Public Health (FOPH), Health and Accident Insurance Directorate ⁵⁴

⁴⁵ Art. 7 let. c and d Microbiology Laboratories Ordinance. The specialist must be able to demonstrate both technical and specific skills in relation to high-risk pathogens.

⁴⁶ MEBEKO: responsible for recognition of foreign postgraduate qualifications covered by the Medical Professions Act.

⁴⁷ There are no federal requirements regarding the licensing of laboratories that pursue activities in other areas of laboratory medicine. Cantonal requirements must be taken into account.

⁴⁸ Art. 42 para. 3 der HIBO. RS 832.102 (Art. 54a para. 1 HIO).

⁴⁹ Laboratories that create DNA profiles within the meaning of HGTA or the DNA Profiles Act must obtain recognition from the Federal Department of Justice and Police (FDJP). The required certificates, skills and practical experience will be assessed during the recognition procedure. Information can be obtained from: Federal Office of Police (Fedpol), Guisanplatz 1A, CH-3003 Bern, biomid@fedpol.admin.ch.

⁵⁰ Chapter 5 of HGTA and DNAPO. DNA profiles for civilian and administrative purposes: a person's specific genetic traits clarified by means of a genetic test and used to clarify a person's parentage or identify that person (Art. 3 let. j HGTA).

⁵¹ Art. 6 para. 1 DNAPO.

⁵² During the recognition procedure within the meaning of the HGTO, the Federal Office of Police will assess whether the qualification held by the applicant is adequate.

⁵³ Art. 6 para. 3 DNAPO.

⁵⁴ The FOPH decides on recognition of equivalence of foreign postgraduate qualifications in the field of laboratory medicine.

Samples taken directly from the person concerned and samples taken from corpses⁵⁵	- SSFM-certified forensic geneticist - or equivalent qualification	Swiss Society of Forensic Medicine (SSFM) ⁵⁶
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DNA profiling in criminal procedures and to identify unknown or missing persons⁵⁷

Samples taken from persons and traces⁵⁸	Both the laboratory director and deputy director must be licensed as forensic geneticists by the Swiss Society of Forensic Medicine (SSFM) or must hold an equivalent qualification. ⁵⁹	Swiss Society of Forensic Medicine (SSFM)
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2.2 Laboratory staff

At least half of all laboratory staff working in the fields of human genetics and microbiology must hold one of the following qualifications.⁶⁰

TESTING TYPE	REQUIRED QUALIFICATION	COMPETENT AUTHORITY FOR RECOGNITION OF FOREIGN QUALIFICATIONS
Human genetics and microbiology		
	Federal qualification as a technician in biomedical testing or foreign qualification recognised as equivalent	Swiss Red Cross (SRC)
	Federal VET diploma as a laboratory assistant (biology) or foreign qualification recognised as equivalent (for microbiological testing, two years of work experience are required)	SERI
	University degree in human medicine, dental medicine, veterinary medicine or pharmacy	Medical Professions Commission (MEBEKO), Undergraduate Training Section
Human genetics		

⁵⁵ Art. 6 para. 4 DNAPO.

⁵⁶ Responsible for examining applications for the recognition of equivalence of foreign postgraduate qualifications in the field of forensic genetics.

⁵⁷ DNA Profiles Act, DNA Profiles Ordinance, FDJP Ordinance on DNA Testing Laboratory Requirements. Legal definition of a DNA profile according to the DNA Profiles Act: *the letter-number combination specific to an individual which is created from the genetic material DNA with the help of molecular biological techniques for the purpose of identifying persons.*

⁵⁸ Section 2 of DNA Profiles Act

⁵⁹ Art. 2 para. 2 let. d of the DNA Profiles Ordinance.

⁶⁰ Art. 13 para. 1 HGTO und Art. 8 para. 1 of the Microbiology Laboratories Ordinance.

	University degree in biology, chemistry, biomedicine, pharmaceutical sciences or life sciences awarded by a Swiss <u>higher education institution</u> or foreign university recognised at national level	Recognition of the foreign qualification is not required in this case as the activities in question are not listed as regulated professional activities in Directive 2005/36/EC. However, swissuniversities may provide guidance on <u>assessment/confirmation of academic level</u> , if this is helpful.
Microbiology		
	University degree in chemistry, biochemistry, microbiology or biology awarded by a Swiss <u>higher education institution</u> or foreign university recognised at national level	Recognition of the foreign qualification is not required in this case as the activities in question are not listed as regulated professional activities in Directive 2005/36/EC. However, swissuniversities may provide guidance on <u>assessment/confirmation of academic level</u> , if this is helpful.

REMARKS

- In microbiological testing, half of the staff must have at least one year of work experience.⁶¹
- When cytogenetic and molecular testing is carried out on gametes and embryos *in vitro* in a process of medically assisted reproduction (Art. 5a RMA⁶²), at least one other person in the laboratory must have sufficient experience in the use of the relevant methods and techniques.⁶³
- In order to work in other areas (including DNA profiles), there are no specific federal requirements with regard to laboratory staff qualifications.

3 Specific details for EU/EFTA citizens who wish to provide services in Switzerland

3.1 Basic principle

In accordance with the Agreement on the Free Movement of Persons (AFMP), professionals who are legally established in the EU/EFTA may provide services in Switzerland without permanently establishing themselves in the country. In such cases, the duration of service provision is limited to 90 days per calendar year.

If the profession they wish to pursue is regulated, they can take advantage of a fast-track verification procedure for their professional qualifications, as set out in EU Directive 2005/36/EC⁶⁴ and the DRPA⁶⁵. **The service provision must be declared in advance to [SERI](#).**

⁶¹ Art. 8 para. 2 of the Ordinance on Microbiology Laboratories.

⁶² Federal Act of 18 December 1998 on Medically Assisted Reproduction; SR 810.11.

⁶³ Art. 13 para. 2 HGTO. During the authorisation process, the FOPH will ascertain whether the level of experience is adequate.

⁶⁴ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, OJ L 255 of 30.9.2005, p. 22, in the current version in accordance with the agreement on the free movement of persons and the revised EFTA Convention.

⁶⁵ Federal Act of 14 December 2012 on the Declaration Requirement and the Verification of Service Provider Qualifications in Regulated Professions, SR 935.01.

3.2 Other requirements

In all cases, persons intending to provide services **must also register with the State Secretariat for Migration** (www.sem.admin.ch > Entry & Residence > Notification procedure for short-term work in Switzerland). This requirement also applies to non-regulated professional activities.

3.3 Who is a service provider?

Service provision is an economic activity carried out on a self-employed basis or without conclusion of an employment contract with a Swiss employer. It is remunerated work of a temporary or occasional nature (limited to 90 working days per calendar year) carried out in Switzerland by an individual who is established in a member state of the EU or EFTA. If you require further information, SERI provides a more detailed note on the service provider concept on its website.

Persons who are not service providers within the meaning of the AFMP will not be able to take advantage of the fast-track procedure for the verification of qualifications. They should instead contact the competent authority to seek recognition of their qualifications under Title III of Directive 2005/36/EC.