



Regulation of professions in the field of

Laboratory Testing

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Introduction

Under the Agreement on the Free Movement of Persons (AFMP¹), 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 authorisation are set out in the Human Genetic Testing Act,² the Human Genetic Testing Ordinance,³ the Microbiology Ordinance,⁴ the Health Insurance Ordinance,⁵ and the DNA Profiling Ordinance.⁶

The equivalence recognition procedure can be found in the [FOPH criteria of 1 September 2019](#) (in French).

It should be noted that the AFMP does not mention any postgraduate qualification in laboratory medicine for Switzerland, which is why there is no automatic recognition of diplomas in this field (see Article 21 of the Directive), and that the general system of recognition defined in Arts 10 to 15 of the Directive applies. In the recognition procedure, postgraduate training in laboratory medicine is compared in each case with the [FAMH postgraduate training required in Switzerland](#) (link in French and German). The reference documents to assess candidate dossiers are:

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

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.

2.1 Laboratory manager

TEST TYPE	TRAINING/QUALIFICATION REQUIRED
Cytogenetic ⁷ and molecular ⁸ testing	<ul style="list-style-type: none">- FAMH⁹ specialist in laboratory medicine- Pathologist, specialist in molecular pathology- University degree in chemistry, biochemistry, microbiology or biology- University degree in human medicine, dental medicine, veterinary medicine or pharmacy- For cytogenetic or molecular analyses of <u>gametes or embryos <i>in vitro</i></u> 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

² Federal Act of 8 October 2004 on Human Genetic Testing (HGTA; SR 810.12).

³ Ordinance of 14 February 2007 on Human Genetic Testing (HGTO; SR 810.122.1).

⁴ Ordinance of 29 April 2015 on Microbiology Laboratories (SR 818.101.32).

⁵ Ordinance of 27 June 1995 on Health Insurance (HIO; SR 832.102). See in particular Article 54 paras 2 and 3 HIO regarding the management of hospital laboratories and laboratories commissioned by other service providers.

⁶ Ordinance of 14 February 2007 on DNA Profiling for Civilian and Administrative Purposes (DNAPO; SR 810.122.2).

⁷ Tests conducted in order to establish the number and structure of chromosomes (Art. 3 let. b HGTA).

⁸ 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).

⁹ <https://www.famh.ch/home-fr-FR/>.

	FAMH specialist in medical genetic analysis or FAMH specialist in laboratory medicine, medical genetics
Diagnostic¹⁰ or epidemiological¹¹ testing	- FAMH specialist in laboratory medicine or equivalent ¹²
Haematology, clinical chemistry, clinical immunology and medical microbiology testing	- FAMH specialist in laboratory medicine or equivalent with four years' formal postgraduate training in the four main fields ¹³
Testing to rule out communicable diseases¹⁴	- FAMH specialist in laboratory medicine able to conduct each type of test - Specialist in haematology as defined in MedPA as well as proof of the professional skills necessary to perform and interpret tests ¹⁵ - or equivalent ¹⁶
Testing of samples taken from the environment¹⁷	- FAMH specialist in laboratory medicine able to conduct each type of test - Diploma in chemistry, biochemistry or biology with two years' professional experience in microbiological testing and proof of the professional skills necessary to perform and interpret tests ¹⁸ - Diploma in microbiology - University degree in human medicine, dentistry, veterinary medicine or pharmacy with two years' professional experience in microbiological testing and proof of the professional skills necessary to perform and interpret tests ¹⁹

¹⁰ Laboratory tests for the detection of a communicable disease in a specific patient (Arts 3, 5 and 6 of the Microbiology Laboratory Ordinance; SR 818.101.32).

¹¹ Laboratory tests for the early detection and monitoring of a communicable disease in the population, and for the prevention and control of that disease (Arts 3, 5 and 6 of the Microbiology Laboratory Ordinance; SR 818.101.32).

¹² The FOPH assesses applications for recognition of equivalence of postgraduate qualifications in laboratory medicine (Art. 54a para. 1 of the Ordinance of 27 June 1995 on Health Insurance [HIO; SR 832.102]).

¹³ Art. 42 para. 3 of the Ordinance of 29 September 1995 on Compulsory Health Insurance Benefits [HIBO; SR 832.112.31]).

¹⁴ 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).

¹⁵ Professionals must be able to demonstrate that they have worked with these systems and technologies and are able to interpret the results.

¹⁶ The FOPH assesses applications for recognition of equivalence of postgraduate qualifications in laboratory medicine (Art. 54a para. 1 of the Ordinance of 27 June 1995 on Health Insurance [HIO; SR 832.102]).

¹⁷ 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 of the Microbiology Laboratory Ordinance).

¹⁸ The professional must be able to demonstrate both technical skills and specialist skills relating to high-risk pathogens. In addition, for degrees in chemistry, biochemistry or biology, two years' professional experience in microbiology analysis are required.

¹⁹ The professional must be able to demonstrate both technical skills and specialist skills relating to high-risk pathogens.

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- or equivalent²⁰
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Establishing DNA profiles for civilian and administrative purposes²¹

Samples taken directly from the person concerned²²

- FAMH Specialist in Laboratory Medicine
- Other qualification guaranteeing required knowledge in the field of kinship and identification

NB: At least two years' practical experience in the field of kinship expertise is required with full responsibility taken for determining at least 100 cases of kinship²⁵

- Forensic geneticist SSML
- Equivalent qualification

Samples taken from corpses²³

The Federal Department of Justice and Police appoints laboratories authorised to conduct DNA testing²⁶

DNA profiling in criminal procedures and to identify unknown or missing persons²⁴

Samples taken from persons

- Forensic DNA testing may only be carried out by recognised forensic genetic testing laboratories the director and deputy director of which hold the title 'forensic geneticist' awarded by the Swiss Society of Forensic Medicine or an equivalent qualification²⁷ (see the documents to be included with an application for recognition as defined in Article 2a of the DNA Profiling Ordinance)
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²⁰ The FOPH assesses applications for recognition of equivalence of postgraduate qualifications in laboratory medicine (Art. 54a para. 1 of the Ordinance of 27 June 1995 on Health Insurance [HIO; SR 832.102]).

²¹ DNA profile: information specific to an individual which is obtained from the non-coding sequences of their DNA using molecular genetic techniques (Art. 3 let. k HGTA).

²² Art. 6 para. 1 DNAPO.

²³ Art. 6 para. 4 DNAPO.

²⁴ 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 Profiling Act; SR 363); Ordinance of 3 December 2004 on the Use of DNA Profiles in Criminal Proceedings and for the Identification of Unknown and Missing Persons (DNA Profiling Ordinance; SR 363.1); FDJP Ordinance of 8 October on the Performance and Quality Requirements for Forensic DNA Testing Laboratories (FDJP Ordinance on DNA Testing Laboratories; SR 363.11).

²⁵ Art. 6 para. 3 DNAPO.

²⁶ Art. 8 DNA Profiling Act.

²⁷ Art. 2 para. 2 let. d DNA Profiling Ordinance.

2.2 Laboratory staff

Half of all staff must hold one of the following qualifications:²⁸

- A federal qualification as a technician in biomedical testing or recognised equivalent foreign qualification.
- A federal VET diploma as a laboratory assistant (biology) or recognised equivalent foreign qualification (for microbiological testing, two years' professional experience is necessary).
- A degree in chemistry, biochemistry, microbiology or biology awarded by a Swiss cantonal university or state-recognised foreign university.
- A degree in chemistry, biochemistry, microbiology or biology issued by a university of applied sciences or a recognised foreign degree in one of these subjects.
- A degree in human medicine, dental medicine, veterinary medicine or pharmacy.

REMARKS

- In microbiology testing, half of the staff must have at least one year's professional experience.²⁹
- When cytogenetic and molecular testing is carried out on gametes and embryos *in vitro* in a process of medically assisted reproduction (Art. 5a RMA³⁰), at least one other person in the laboratory must have sufficient experience in single-cell testing (see RMO³¹).³²

3 Authorities responsible for recognising qualifications

There are various authorities authorised to recognise the required qualifications:

QUALIFICATION	COMPETENT AUTHORITY
Specialist in Laboratory Medicine (FAMH specialist)	Federal Office of Public Health (FOPH) Health and Accident Insurance Directorate ³³
Postgraduate qualification in medicine ³⁴ (e.g. specialisation in pathology)	Commission for Medical Professions (MEBEKO), Postgraduate Training Section ³⁵

²⁸ Art. 7 para. 1 HGTO and Art. 8 para. 1 of the Ordinance on Microbiology Laboratories.

²⁹ Art. 8 para. 2 of the Ordinance on Microbiology Laboratories.

³⁰ Federal Act of 18 December 1998 on Medically Assisted Reproduction, SR 810.11.

³¹ Ordinance of 4 December 2000 on Medically Assisted Reproduction, SR 810.112.2.

³² Art. 7 para. 2 HGTO.

³³ <https://www.bag.admin.ch/bag/en/home/das-bag/organisation/direktionsbereiche-abteilungen/direktionsbereich-kranken-unfallversicherung.html>

³⁴ Art. 2 of the Ordinance of 27 June 2007 on Higher Education Qualifications, Degree Programmes, Continuing Education and Training and Professional Practice within the Medical Field (MedPO; SR 811.112.0).

³⁵ <https://www.bag.admin.ch/bag/fr/home/das-bag/organisation/ausserparlamentarische-kommissionen/medizinalberufekommission-mebeko/mebeko-ressort-weiterbildung.html> (not available in English)

Graduate qualification in a medical profession	Commission for Medical Professions (MEBEKO) Graduate Training Section ³⁶
University degree in Chemistry, Biochemistry, Microbiology or Biology	It is not necessary to obtain recognition of a foreign degree in these instances as this is not a regulation as defined in Directive 2005/36/EC. However, swiss-universities ³⁷ may draw up <u>recommendations for recognition</u> if these are considered useful.
Federal diploma, biomedical testing technician	Swiss Red Cross (SRC) ³⁸
Federal VET Diploma, Laboratory Assistant	SERI ³⁹

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

4.1 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/EC⁴⁰ and the DRPA⁴¹. **The service provision must be declared in advance to SERI⁴².**

4.2 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.

³⁶ <https://www.bag.admin.ch/bag/fr/home/das-bag/organisation/ausserparlamentarische-kommissionen/medizinalberufekommission-mebeko/mebeko-ressort-ausbildung.html>.

³⁷ <https://www.swissuniversities.ch/fr/services/reconnaissance-swiss-enic/>.

³⁸ <https://www.redcross.ch/fr/reconnaissance-des-titres-professionnels-etrangers/reconnaissance-des-titres-professionnels-1>.

³⁹ <https://www.sbf.admin.ch/sbf/fr/home/formation/reconnaissance-de-diplomes-etrangers/procedure-de-reconnaissance-lors-dun-etablissement-en-suisse/procedure-au-sefri/deroulement-et-duree.html>.

⁴⁰ 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

⁴¹ Federal Act of 14 December 2012 on the Declaration Requirement and the Verification of Service Provider Qualifications in Regulated Professions, SR 935.01.

⁴² www.sbf.admin.ch/declaration

4.3 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.