Centre Suisse de Contrôle de Qualité
Schweizerisches Zentrum für Qualitätskontrolle
Centro Svizzero di Controllo della Qualità
Quality Control Centre Switzerland

Handbook

SPTS 0004

Services suisses d'essais d'aptitude
Schweizerische Eignungsprüfungsdienststellen
Servizi svizzeri di prove valutative interlaboratorio
Swiss proficiency testing services

Quality Control Centre Switzerland - CSCQ

Your participant number

Each participant is allotted its own identification number (ex.: Laboratory No 9997). It must be indicated whenever exchanging information with the CSCQ. It appears on the bottom right corner of each document addressed to you personally. Your identification number is personal to you and allows to treat your data confidentially.

Opening hours and phone numbers

The CSCQ is open Monday to Friday from 8:30 A.M. to noon and 1:30 P.M. to 4:30 P.M., except on public holidays. Outside of these office hours, leave a message on our answering machine or send us an e-mail.

- Technical questions, answers in English +41 22 305 52 36
- Technical questions, answers in French +41 22 305 52 30
- Technical questions, answers in German +41 22 305 52 31
- Technical questions, answers in Italian +41 22 305 52 32
- Secretariat: registration and registration changes +41 22 305 52 36

Contact information

CSCQ
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CH - 1225 Chêne-Bourg

Website: http://www.cscq.ch
E-mail: cscq@hug.ch
Code GLN: 760 100 132 6507

Official recognition

QUALAB – Schweizerischer Verein für Qualitätsentwicklung im medizinischen Laboratorium
QUALAB – Association suisse pour le développement de la qualité dans les laboratoires médicaux
QUALAB – Associazione svizzera per la promozione della qualità nei laboratori medici

The CSCQ has been recognised by the QUALAB (Swiss association for quality development in the medical laboratories) as an official control centre for the quality of medical analysis since its foundation.

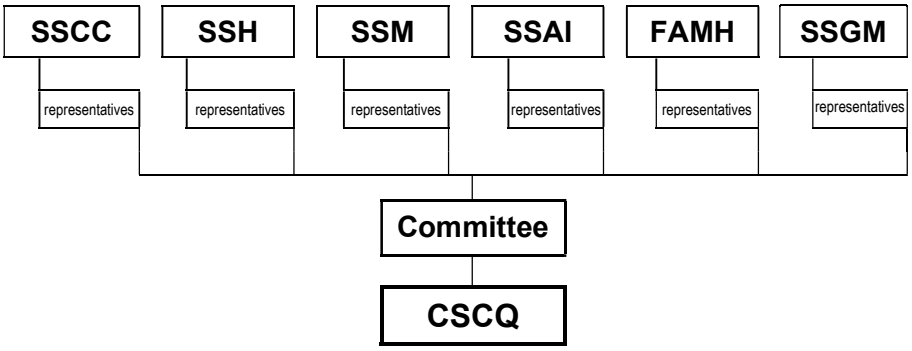
The CSCQ is accredited by the Swiss Accreditation Service (SAS) with respect to the International Organisation for Standardization ISO 17043, thus being recognised as a proficiency testing service on the Swiss, European and International level. Its accreditation number since 2012 has been SPTS 0004 (SPTS - Swiss Proficiency Testing Services).

FAMH
DIE MEDIZINISCHEN LABORATORIEN DER SCHWEIZ
LES LABORATOIRES MÉDICAUX DE SUISSE
I LABORATORI MEDICI DELLA SVIZZERA

Le The CSCQ has been recognized as a FAMH formation centre for clinical chemistry, category C, since 2006 and for haematology since 2016.

The Quality Control Centre Switzerland

- The Quality Control Centre Switzerland is a non-profit association established in 1972. Its committee is composed of two delegates from each of the following professional and scientific societies:
  - the Swiss Medical Analysts Association (FAMH)
  - the Swiss Society of Clinical Chemistry (SSCC)
  - the Swiss Society of Hematology (SSH)
  - the Swiss Society for Microbiology (SSM)
  - the Swiss Society for Allergology and Immunology (SSAI)
  - the Swiss Society of Medical Genetics (SSGM)



These representatives are consulted on the choice of the proposed programs in their field (see the appendix entitled «Members of the Committee»).

- The CSCQ also has significant interactions with other scientific societies for which it organises EQA surveys.
- The CSCQ has the following two main assignments:
  - offering external quality surveillance to interested individuals or professionals (medical practices, private laboratories, hospital laboratories, pharmacies, veterinarians, dental practices, schools, etc.)
  - organising regular surveys, in order to allow registered laboratories to compare their mutual results, and to compare their results to those obtained with recommended or reference methods.

Introduction

- This handbook optimises the conditions for External Quality Assessment (EQA) of your analyses for which you receive samples of control material from the CSCQ. It is therefore important to read it carefully and keep it for future reference. Inter-laboratory surveys, proficiency testing, and external quality assessment all refer to the same service.
- As all CSCQ services, this handbook is available in French, German, Italian, and English. When the person responsible for quality assessment changes, the handbook must be given and explained to the new person in charge. The current version of each document is available on the website www.cscq.ch.

Confidentiality

- The CSCQ staff is bound by professional secrecy.
- The CSCQ guarantees that each participant's individual or group results remain fully anonymous. Your participant number is therefore only to be used when exchanging information with the CSCQ and must not be transmitted to third parties. You are the only one receiving the report on your results. The CSCQ does not communicate your data to anyone beyond its legal obligations.
- By contrast, when becoming a CSCQ member, the Swiss laboratory authorises the CSCQ to transfer the participation and quality assessment data of its EQA on the QUALAB data assessment platform. The QUALAB quality contract also requires that the Swiss laboratories authorise the QUALAB to transmit these data in the form of an annual participation at the national level to a third party, in accordance with art. 58c al. 3 of the LAMal.
- If your laboratory is part of a network (i.e. a group of private or hospital labs), the person in charge of the network may be sent a copy of your results and it should inform you about his receiving.

Legal requirements

- Good laboratory practices require internal and external quality assessments for each parameter. Legal requirements concerning external quality assessments are issued by the QUALAB, the competent Swiss association deciding whether an assessment is compulsory or not. The CSCQ keeps you informed, enables you to meet these requirements and to comply with existing regulations.
- The QUALAB quality assurance contract requires Swiss laboratories to authorise their chosen control centres to transfer data on their participation and the quality assessment of their external controls to the QUALAB data exchange platform. The laboratories authorise QUALAB to transmit this data to third parties, in accordance with Art. 58c para. 3 of the LAMal, in the form of an annual national participation list.
- Existing QUALAB requirements are available on www.qualab.swiss. They are currently as follows:
  - ♦ register with QUALAB
  - ♦ participating in at least 4 surveys a year for each parameter
  - ♦ obtaining 75% of satisfactory results for each measured parameter, unless otherwise stipulated. The specific requirements for each parameter are listed in the QUALAB table
  - ♦ comply with internal quality control (IQC) requirements in accordance with the QUALAB directive (self-declaration)
  - ♦ monitor the continuous improvement process in the event of inadequate EQA results
- The main current requirements can be found on our website in the appendix entitled «Legal requirements».
- EQA also allows to show your work performance to third parties (patients, social security, authorities, etc.).

Outsourcing

- EQA samples are **never** to be sent to an external laboratory for analysis. In order to comply with legal requirements, control samples are to be analysed as a patient sample, by the laboratory returning the results.
- You must be able to certify that the returned results were obtained in your own laboratory. Kindly sign each result form to confirm it. As far as EQAcom users are concerned, transferring the results through EQAcom is considered as an electronic signature.
- A laboratory should never accept to analyse an EQA sample for another lab. If you have any doubt, the FAMH advises you to protect yourself as follows in your report:
  This result is solely an internal verification of your own laboratory values and does not allow you to escape from legal requirements on quality assessments.

Programmes

The various programmes provided by the CSCQ are detailed in the specific appendices.

Methods and instruments

- The CSCQ maintains an up-to-date list of the assessed methods.
- Depending on the parameter, a quantitative, by discrete values or qualitative assessment analysis is performed (see appendices entitled «Assessments» and «Reports»).
- Each parameter can be assessed with different methods. Precise identification of the method applied for its determination allows for proper comparisons of results obtained with the same analytical method or with different methods. When registering, you have to indicate the device and/or reagent name you use to ensure a correct interpretation of your results. You will be reminded of this information with each sample sent.
- Results for a given parameter with the same sample can be quite different depending on the method and/or the analytical system, enzymes being obviously the best examples. Thus, depending on the coding of your analytical method, *your results may be accepted or rejected* if outside the tolerance interval. We thank you to keep us immediately informed of any changes by phone or in writing.
- Modifications are to be reported by phone or in writing at least five weeks before sending the samples for them to appear on the screen or on the result forms of the ongoing survey. Modifications sent during the survey will be taken into account whenever possible.
- For some parameters, several analytical systems can coexist in order to avoid statistical bias due to numerous participants using the same method. This particularly applies to closed systems, instruments requiring a specific sample, and to enzymes. In such cases, a separate assessment is performed.

Specific features of methods and instruments

Several instruments have specific operating requirements to analyse control samples. Instructions for use are provided by the manufacturer or are available on the CSCQ website (under documents / device handbooks and EQA samples manipulation).

Registration, participation and cancellation

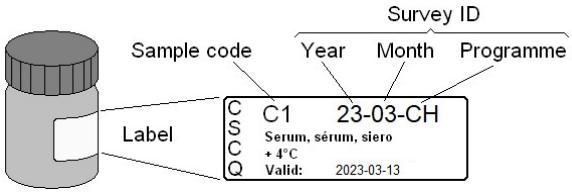
- The laboratory must contact the CSCQ and specify the parameters which are analysed and the methods used. The laboratory then receives control samples at the frequency chosen in its registration and according to the selected analyses. The lab returns its results and receives an assessment report with its performances. Comments included in the report are an opportunity for the lab, if requested, to improve its performances. EQA is also useful for highly standardised methods (closed systems, dry chemistry) to check the quality of the analytical work and the validity of instruments and reagents.
- All your registered data appear on your subscription's confirmation, including the following information that should be checked:
  - the complete identification of the laboratory, including RCC number and GLN codes for Swiss laboratories,
  - the programmes and parameters for which you registered,
  - the methods, reagents, and instruments.
- Upon request, the CSCQ can mail invoices to a billing address which might be different from the contact one. Samples can also be sent to another address, especially for storage quality purposes (the address of another lab will not be accepted).
- The registration is renewed tacitly from year to year. The member may cancel its registration for the next year by sending a registered post or by e-mail, not later than on 31st August of the current year.

Multiple assessments

- Laboratories using different methods for certain parameters may return one result for each of them. They have several identification numbers, but only one membership is invoiced.
- The method is to be properly described and associated with the result obtained when using it.

Receiving control samples

- The « Calendar » appendix shows the sample dispatch dates for all surveys. A new appendix is issued each year and automatically sent with your report at the end of the year.
- The samples shipping dates for the next survey of a programme you are registered for are mentioned in each programme survey report.
- Samples are essentially sent by post. You should receive them the day after the dispatch date or within two days. Should the sample be damaged during shipping, you will have to contact directly your local post office where a claim form is to be filled out. You must contact us if you do not receive the parcel.
- If possible, sample dispatch can exceptionally be postponed by one week. However, the deadlines to return your results cannot be changed.
- The sample code is written on the vials you receive for each survey. The meaning of the different codes is explained in the appendix of each programme.



Validity date: 13 March 2023

Precautions

- Except for the material used in virology surveys, the biological liquids were tested negative for anti-HIV antibodies, anti-HCV antibodies, and HBs antigen. However, the presence of pathogens can never be ruled out, in particular in microbiology surveys.
- Thus, any sample must be considered as potentially infectious and should be disposed as a patient sample.

Sample specific features

- The CSCQ checks the stability and the homogeneity of the in-house proficiency test items, according to the ISO 13528 Annex B.3 (Formula to check the homogeneity), in duplicates analysis. For purchased conditioned samples they are assessed by the subcontractor and confirmed by the CSCQ.
- The CE conformity marking does not have to be affixed on EQA samples which are considered as performance assessment tools and thus exempt as such.
- For each survey, the participant receives one or several control samples, depending on the programme it is registered for. The samples to be used are indicated in the programme description appendix. They are also mentioned on the screen or in the first column of each result form.
- We provide material adequate to the analyses to be performed in our programmes. As in routine analyses, these samples can have physiological or pathological high/low concentrations. High concentration control samples must not be diluted.
- We only use specific control material for a given analytical system when regular samples do not allow correct dosage with that particular system.
- Samples can be lyophilised or liquid, whole blood (B), serum (S), plasma (P), urine (U), or other specific control material. Unless otherwise stipulated, samples must be stored in the dark and in the refrigerator (+ 2 to + 8 °C). They should never be frozen.
- Apart from the possible reconstitution procedure, these samples must be treated as patient samples, which means using the same procedure and repeating the analysis only if you would repeat it for the patient sample under equal conditions.
- Control sample analysis must be performed as soon as you receive the samples or within the indicated time limits at the latest. Information specific to some parameters can be found in the appendices of each programme.
- Additional samples can be provided within the limits of available stock, and will involve additional costs.
- A control sample is never ever to be used as a standard.

Measurement units

- Results must be reported in the units which are recommended in Switzerland, in particular SI units (International System of Units). The litre (L) is the recommended unit of volume. For example, use g/L instead of g/dL for hemoglobin and MCHC.
- You can submit your result with unit used by your device by choosing it in the EQAcom scroll menu.
- Reminder: the character E is for power. Thus, 10 E12/L means «10 to the 12th power (10^{12}) per litre».
- You can find a useful document under:
  http://www.cscq.ch/SiteCSCQ/FichierPDF_EN/FT-Conversion-Factors.pdf

Returning the results

- The deadlines to return the results are the very last dates for the CSCQ to receive your results. They cannot be postponed. If we receive your results after this date, they will not be assessed. You will then receive a global report mentioning that they were «not received».
- Some laboratories using several instruments adjust their values in order to have identical patient results whatever the analytical method used. These laboratories must return their results without any adjustment.
- The CSCQ advises you to keep a record of the results you obtained with the control samples. Potential errors will be easier to track down if your assessment is not satisfactory.
- For each survey, you receive a parcel with one or several control samples, together with a certificate of delivery. This certificate lists the surveys you are participating to for the current month as well as the analytes to be assessed for each of them, the sample(s) to be used, and any additional information. A result form can be printed out from EQAcom for personal use only and should not be returned to the CSCQ where the data will not be captured.
- If your result falls outside of the measurement range of your instrument, put « < » or « > » before your value.

Electronic result transfer - EQAcom

Using EQAcom, a simple, user-friendly programme, means that results can be transmitted electronically, and reports can be easily consulted and archived. All you need is Internet access. The reports are available for 12 months, and the results transmitted are accessible for 24 months. After the respective periods mentioned, these documents are no longer directly accessible on EQAcom and any request for a copy of a report will be invoiced according to the CSCQ price list. The CSCQ staff will be happy to provide you with any information you may require.

Point of care testing (POCT)

EQA for POCT is included in the various specific programmes. This approach allows for an easier organisation, a greater number of participants for statistical assessments, and a possible comparison of the different analytical systems.

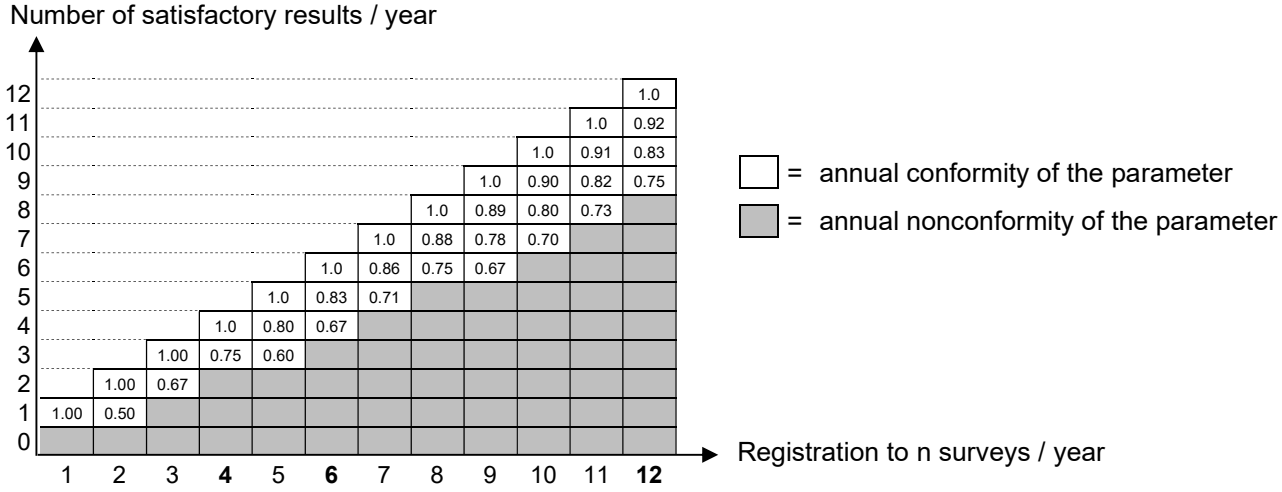
Procedure to be followed when the assessment criteria are not met

The non-compliance of the analysis tolerance ranges according to the QUALAB assessment criteria activates the quality continue improvement actions as described in the DQ concept or in the quality contract.

QUALAB, Contrat d'assurance qualité, 2022, chap. 6 and Concept QUALAB, 2022, chap. 5.8.4.

Participation certificate

- At the beginning of each year, a certificate is sent to the members and made available to them in their EQAcom account. It covers the previous year and includes all information that may be requested by the Authorities regarding the parameters for which your laboratory has submitted results for EQA. The CSCQ certificate certifies your participation in external quality assessment programs and can be submitted upon request to your umbrella association (in Switzerland: FMH, FAMH, H^+, pharmaSuisse, etc.).
- The certificate thus contains the following information:
  - the name, address, and laboratory RCC number, GLN code for Swiss laboratories and QUALAB-GLN-laboratory code,
  - the period covered for each parameter,
  - the analyses submitted to EQA by the laboratory,
  - the number of registration and of results returned for each parameter,
  - the evidence that tolerance limits are met - or not - for each parameter as set forth by the QUALAB (participation and quality) and the CSCQ one's (quality).
- On the annual certificate, the ratio between the number of satisfactory results and the total number of results (surveys) is rounded. Hence, annual conformity is obtained when at least 1 in 2 result is satisfactory, 3 in 4, 4 in 6 or 9 in 12, depending on the annual number of surveys. The following diagram shows all possible conformities.



- Copies of certificates can be sent upon request, which will involve additional costs.

Continuing education

EQA should never be considered as an administrative constraint but as a continuing education opportunity when analysing out-of-tolerance results, investigating the root causes of operational deficiencies and implementing corrective actions.
Several scientific organisations acknowledged this educational role and grant a certain number of credits which are indicated in some EQA descriptive sheets (pre-/post-analytic, dermatology-mycology, etc.).

EQA recordkeeping

- Results, reports, improvement actions and certificates are to be kept electronically, or in paper form, for 5 years in order to provide proof of your participation, if required for an inspection for instance.

  Critères de fonctionnement des laboratoires d'analyses médicales (CFLAM) 3.0, 2016, chap. 4.1.

- Using EQAcom facilitates both recordkeeping and traceability. EQAcom procedures are recognised by the QUALAB.

Internal Quality Assessment (IQA)

Legal requirements and «Criteria for laboratory practice in medical analysis» (CFLAM) include regular IQA along with EQA. Laboratory heads are responsible for IQA which can be considered as self-assessment of measurement accuracy.

Terms of participation

- General terms of registration are given in the appendix entitled «Registration» which can be used as a registration form.
- Registration is valid for one year but can be initiated during the course of the year. An annual invoice is sent at the beginning of each year and includes all the programmes you registered for. Fees for the CSCQ programmes and services are listed in the «Fees list» appendix. The billing codes of the different surveys can be found in each program descriptive sheet. Another invoice may be sent for additional services, or for the prorated charges corresponding to registrations initiated during the course of the year.

Corporate name and bank details

Corporate name:	Centre Suisse de Contrôle de Qualité des Analyses de Biologie Médicales
Commercial Register:	GE 7145 / 1999
VAT:	CHE - 108.125.605
Bank:	UBS SA, Route de Florissant 59, CH - 1206 Genève
Clearing:	0240
Swift code:	UBS WCHZH80 A
IBAN (International Bank Account Number):	CH42 0024 0240 3849 9829 H
BIC (Bank Identifier Code) :	UBSWCHZH80A

Update of the handbook and its appendices

- Updating your handbook in order to optimise the EQA implementation is under your responsibility.
- The handbook consists of several documents, some of which are sent when you first register. The latest updates of all documents are available on the CSCQ website (www.cscq.ch).
- Paper copies of these documents may be provided upon request.

Complaints

While every effort is made to ensure the quality of our services, you may not be fully satisfied: please, let us know so that we can respond adequately and improve our services. All complaints and disputes are dealt with in accordance with our quality assurance system.

P e r s o n a l n o t e s