Quality Control Centre Switzerland - CSCQ

1. 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.

2. Opening hours and phone numbers

The CSCQ is open Monday to Friday from 8:30 A.M. to noon and 2:00 P.M. to 5:00 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
- Fax	+41 22 305 52 38

3. Contact information

CSCQ
2, chemin du Petit-Bel-Air
CH - 1225 Chêne-Bourg

Website: http://www.cscq.ch
E-mail: cscq@hcuge.ch
GLN No: 760 100 132 6507

4. Official recognition

QUALAB
SCHWEIZERISCHE KOMMISSION FÜR QUALITÄTSSICHERUNG IM MEDIZINISCHEN LABOR
COMMISSION SUISSE POUR L'ASSURANCE DE QUALITÉ DANS LE LABORATOIRE MÉDICAL
COMMISSIONE SVIZZERA PER L'ASSICURAZIONE DI QUALITÀ NEL LABORATORIO MEDICO

The CSCQ has been recognised by the QUALAB (Swiss Commission for Quality Assurance in the Medical Laboratory) as an official control centre for the quality of medical analysis since its foundation.

SWISS PROFICIENCY TESTING

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 004 (SPTS - Swiss Proficiency Testing Services).

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

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

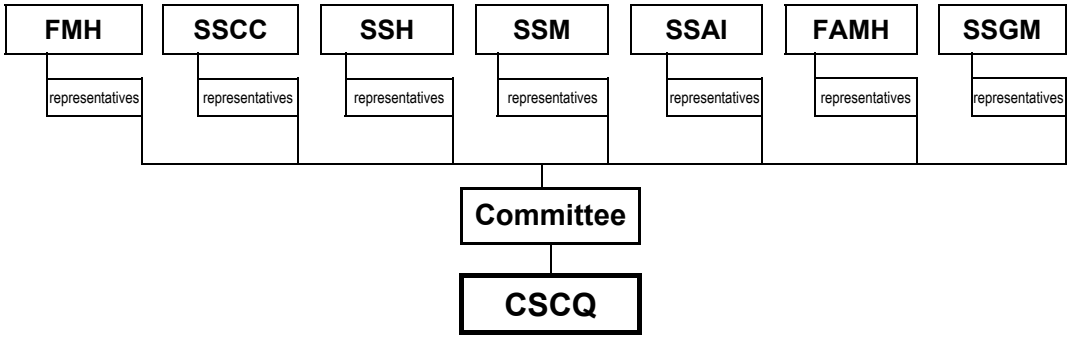
5. Introduction

- 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.

6. The Quality Control Centre Switzerland

- The Quality Control Centre Switzerland is a non-profit association established in 1972 by professional and scientific societies such as:
  - the Swiss Medical Analysts Association (FAMH)
  - the Swiss Medical Association (FMH)
  - 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 (SSMG)

  The CSCQ also has significant interactions with other scientific societies for/or with which it organises EQA surveys.
- Professional societies (FMH and FAMH) and scientific ones (SSCC, SSH, SSM, SSAI, and SSGM) appoint two representatives to the CSCQ Committee. The representatives are consulted on the choice of the programs in their field. They are listed in the appendix entitled "Members of the Committee".



- 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.

7. Confidentiality

- Your identification number is personal and allows your data to be confidential.
- 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. It 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. Upon the QUALAB request, competent professional Societies (FMH, FAMH, H^+, pharmaSuisse, etc.) may check the participation to EQA directly with the CSCQ.
- 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 should inform you about his receiving it.

8. 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 organisation 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.
- Existing QUALAB requirements are available on www.qualab.ch. They are currently as follows:
  - participating in at least 4 surveys a year for each parameter
  - obtaining 75% of satisfactory results for each parameter, unless otherwise stipulated. The specific requirements for each parameter are listed in the QUALAB table.
- The main current requirements can be found in the appendix entitled «Legal requirements».
- EQA also allows to show your work performance to third parties (patients, social security, authorities, etc.).

9. Outsourcing

- EQA samples are never to be sent to an external laboratory. 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 analysed 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.

10. Programmes

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

11. Methods and instruments

- The CSCQ maintains an up-to-date list of the assessed methods.
- Depending on the parameter, a quantitative, semi-quantitative 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 method you use to ensure a correct interpretation of your results. If you have any doubt on the method used, you may request assistance from the sale representative of your instrument/reagent manufacturer, or from the CSCQ. This information is remind to you on each distribution. We thank you to keep us immediately informed of any changes by phone or in writing.
- 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 enzymes. In such cases, a separate assessment is performed.
- 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, *your results may be accepted or rejected* depending on the coding of your analytical method.
- 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.

12. 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. You can find some of them in the dedicated appendix of a given programme.

13. Participation

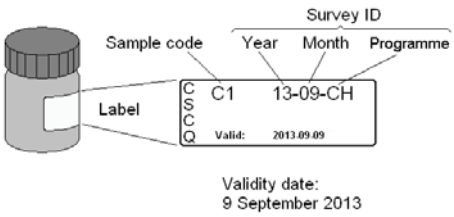
- The laboratory must contact the CSCQ and specify the parameters which are analysed and the methods used. The laboratory then receives control samples on a regular basis according to the type of registration and the selected analyses. The lab returns its results and receives an assessment report with its performances being compared to both all participating laboratories and to those using the same operating method. Comments included in the report are an opportunity for the lab 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 data appear on the confirmation of your registration, including:
  - the complete identification of the laboratory
  - 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).

14. Multiple assessments

- Laboratories using different methods for certain parameters may return one result for each of them.
  - If the method is included in the same analytical system, the laboratory must have several participant numbers (several instruments and/or identical methods).
  - If the method is not included in the same analytical system, the second (or n^{th}) method can be included in the first registration.
- In each case, the method is to be properly described and associated with the result obtained when using it. Please contact the CSCQ if interested.

15. 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.
- Samples are 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 (depending on samples expiry dates), sample dispatch can 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:
9 September 2013

16. 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.

17. Sample specific features

- 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 survey he is registered for. The samples to be used are indicated in the programme description. They are also mentioned in the first column of each result form or on the screen.
- 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 samples must be diluted if you are used to doing so for patient samples in everyday practice.
- 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 + 6 °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.

18. 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.

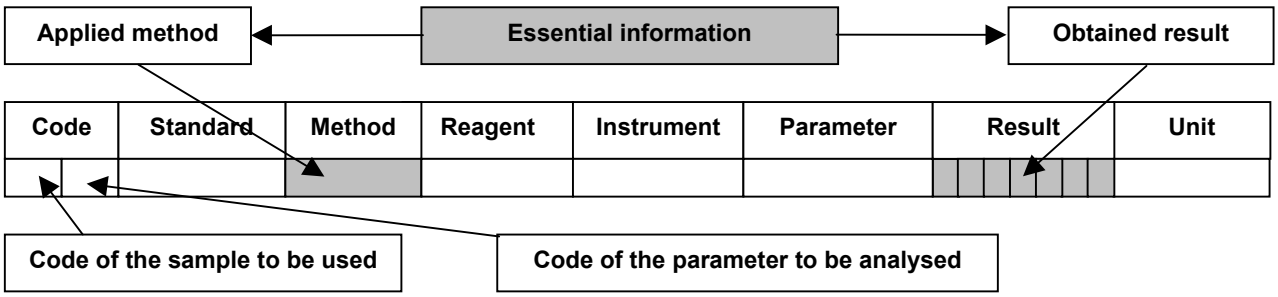
19. Measurement units

- 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.
- Reminder: the character E is for power. Thus, 10 E12/L means «10 to the 12th power per litre».
- For pressure (pO_2, pCO_2), the recommended unit is kPa.
- Upon request, we can send you a complimentary brochure with the conversion factors to be used.

20. Result form and delivery slip

- Results should preferably be returned with EQAcom, the dedicated software, or by post. Faxes are not always clearly legible.
- Results are to be returned only *once* without using several transmission channels simultaneously.
- For each survey, you receive a parcel with one or several control samples, together with the following:
  - a delivery slip, *if you use EQAcom*. This paper lists your surveys 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 as described below 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.
  - a result form for each survey (see description below), *if you do not use EQAcom*. This form lists the analytes for which you registered and the sample(s) to be used. It must be completed and returned to the CSCQ.

- Your identity is mentioned on these forms, as well as the sample code(s), the parameters to be analysed and the analytical system that you use. You only have to check these preprinted data and add your results in the appropriate boxes. You can also modify the preprinted information if any changes regarding your methods, instruments or address. *Whatever you write should be legible*.



- Please beware of:
  - the preprinted units,
  - the position of both the decimal point and the decimals. Do not use « – » or « / ».
- If your result falls outside of the measurement range of your instrument, put « < » or « > » in the first box.
- Results with more than 5 digits for the whole number part will be reported within the available boxes, regardless of the position of the decimal point. Examples of results:

Code		Standard	Method	Reagent	Instrument	Parameter	Result									Unit
C1	3	Closed	SpotReady	AxonLab KDK	Spotchem EZ SP 4430	S-Ca					***2***	***,***	***2***			mmol/L
C1	10	Closed	Réflotron	Roche	Reflotron	S-Urates			***4***	***6***	***7***	***,***				mmol/L
T1	65	Dade	Innovin	Innovin	Sysmex CA	P-PT INR					***1***	***,***	***7***			INR
T1	66	Closed	CoagCheXSP	Roche	Coaguchek XS Plus	P-PT %				***4***	***1***	***,***				%
CR	700	Closed	NycoCard	Axis-Shield	NycoCard Reader II	S-CRP	**<**				***6***	***,***				g/L
K1	6500	---	CoagCheXSP	---	---	Lot Coaguc	***2***	***0***	***1***	***4***	***0***	***,***	***2***	***0***	***0***	-

21. Point of care testing (POCT)

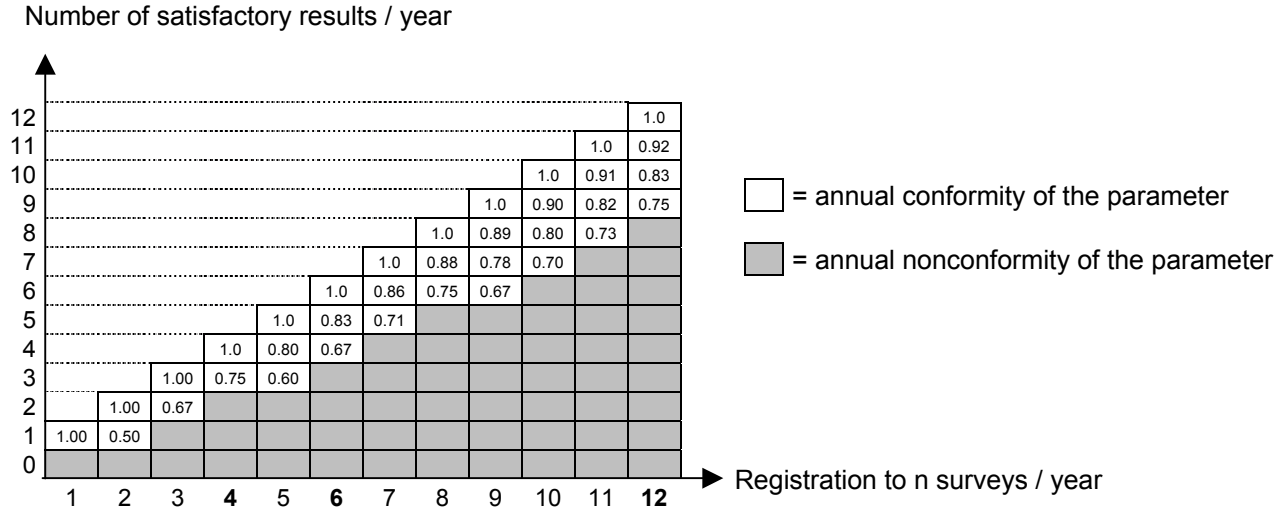
EQA for POCT is included in the various specific programmes. This approach allows for an easier organisation, a greater number of participants for statistical assessments, and a possible comparison of the different analytical systems.

22. Electronic result transfer - EQAcom

An easy and user-friendly software is available on the Internet for result transfers. The CSCQ staff is at your disposal should you require any information. Using EQAcom makes you save 56% of your registration fee.

23. Participation certificate

- At the beginning of each year, a participation certificate is sent to participants. It covers the previous year and includes all information that may be requested by the Authorities regarding the parameters for which you have an EQA registration. The CSCQ certificate certifies your participation in external quality assessment programs and can be submitted upon request to your umbrella association (FMH, FAMH, H^+, pharmaSuisse, etc.)
- The certificate thus contains the following information:
  - the name, address, and laboratory RCC and GLN numbers
  - the period covered by the certificate
  - the analyses submitted to EQA by the laboratory
  - the number of results returned for each parameter
  - the evidence that tolerance limits are met - or not - for each parameter as set forth by the QUALAB.
- On the annual participation 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 results 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.

24. 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.).

25. EQA recordkeeping

- Digital or paper result forms, reports, and certificates are to be kept for 5 years in order to provide proof of your participation, if required.
- Using EQAcom facilitates both recordkeeping and traceability. EQAcom procedures are recognised by the QUALAB.

26. 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.

27. 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. At the end of the year, a second invoice may be sent for additional services, or for the prorated charges corresponding to registrations initiated during the course of the year.

28. Bank details

Bank	:	UBS SA, Route de Florissant 59, CH - 1206 Geneva
Clearing	:	0240
Swift code	:	UBS WCHZH12A
IBAN (International Bank Account Number)	:	CH42 0024 0240 3849 9829 H
BIC (Bank Identifier Code)	:	UBSWCHZH80A
VAT	:	CHE - 108.125.605
Commercial Register	:	GE 7145 / 1999

29. Update of the handbook and its appendices

- You are responsible for updating your handbook in order to obtain good EQA performances.
- 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.

30. 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