

## SKML General Terms and Conditions

### 1. Definitions

- SKML:** The aim of the Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek (Foundation for Quality Assessment in Medical Laboratory Diagnostics) is: to promote the quality of medical laboratory investigation involving diagnostics and treatment and to maintain it at a standard which ensures that patient diagnosis and treatment are optimally supported.
- Section:** The SKML is divided into a number of sections each of which is responsible for its own field of expertise.
- Participant:** Laboratory (group of one or more departments or units that are closely related in terms of organisation and logistics) that registers for and participates in the external quality control of the SKML. A participant can take part in the quality control of one or more sections, taking part in the entire programme as well as parts of the programme; in other words it may participate in some schemes of the section programme, while not participating in others.
- Scheme:** A number of (one or several) surveys for external quality control of one or more analytes that are related in terms of their subject content for which participants may register.
- Survey:** A survey comprises the entire process of external quality control, from the formulation of a problem, choice, composition, production and distribution of one or more samples that is/are to be examined by the participant to the processing and reporting of the results returned by the participants, discussion, evaluation, etc. A scheme includes one or more surveys per calendar year, each of which has a commencement date and a deadline date for submission.
- Sample:** A research specimen that is to be investigated by a participant in the context of a survey.
- Result:** Result of investigation of the sample by the participant. This may consist of:
- The result of the technical analysis,
  - The professional (clinical) interpretation of the result of the technical analysis,
  - The information to be provided by the participant on the manner in which and/or resources used to achieve the result,
- A combination of the above possibilities.  
This result may include an individual score, a result in relation to a reference value, a result in relation to a result from an expert laboratory, a result in relation to other – anonymised – participants, a result relative to a weighted value, or otherwise.

### 2. Applicability of these General Terms and Conditions

These General Terms and Conditions are applicable to every agreement that is concluded in writing or orally between the SKML and the participant, unless otherwise explicitly provided in writing by individual agreement.

### 3. Execution of the agreement

The SKML seeks to achieve its aim by implementing External Quality Assessment Schemes (EQAS). The SKML will initiate such schemes, and will determine the nature and time of the different schemes in which the participants may take part. Participants may register for different schemes and will receive a result of their participation and possibly also a certificate.

Participation in schemes is reserved for medical laboratories that want to verify the accuracy of their findings by comparing them with other participants and, where available, reference or expert values. Participation by suppliers of IVD articles is permitted if the aim is to better understand the analytical performance of their own products and thus be able to better

support their own customers. Commercial expressions in any form based on or with reference to SKML reports, or results of participation, are not allowed. No participant is allowed to make the reports of the SKML available or transparent outside their own institution without the prior written permission of the SKML.

The SKML has an obligation to use its best endeavours to organise and implement the schemes. The SKML will execute the agreement to the best of its ability and understanding in accordance with high professional standards and in the light of scientific knowledge available at such time. In this respect the SKML seeks to obtain accreditation by the Dutch Accreditation Council RvA (Raad voor Accreditatie).

The individual results of the participants in a scheme can be inspected by the chairman of the section concerned, or his/her mandated replacement. In the light of the results, he/she may contact the participants in order to discuss those results and to give advice on improving performance.

If and to the extent required in the interest of ensuring the proper execution of the agreement, the SKML may arrange to have certain work performed by third parties, being independent bodies. The SKML outsources certain support activities to selected suppliers as far as permitted by ISO / IEC 17043: 2010. The SKML monitors the conformity and suitability of such services.

The participant will ensure that all data which the SKML indicates are necessary or in respect of which the participant is reasonably aware that such data are necessary in order to permit the execution of the agreement are provided to the SKML within the agreed timeframe.

#### 4. Term of the contract

The agreement is entered into for an indefinite period, unless otherwise explicitly agreed in writing between the parties.

#### 5. Participation

In order to obey the intention of a scheme, the participant guarantees the following aspects when participating:

- The samples are received, processed and treated as much as possible (within the instructions in the sample package insert) as samples in the regular patient care of the participant concerned;
- All actions, from receipt to interpretation and reporting, are taken care of as much as possible by the staff who would also take care of a comparable request in regular patient care;
- In order to come to a result for the SKML, the participant does not perform any other analyses or operations than for a comparable application in the regular patient care of the relevant participant.

#### 6. Responsibilities of participants regarding samples

- The samples received by the participants may not be made available to third parties;
- The delivered material may only be used for the purpose of the scheme, including analyses for (corrective) actions in response to the results of participation;
- Despite testing, the material supplied may be potentially infectious. The participant is aware of this and therefore considers and treats the materials as potentially infectious in a manner comparable to the regular patient care of the relevant participant;
- All instructions, also those based on test results that became available after delivery, that give cause to destroy the material, must be followed immediately;
- The participant will immediately report this to the SKML if he/she experiences health effects as a result of exposure to SKML sample material;
- If the destruction of material is desired, the participant will confirm this destruction to the SKML.

7. Control Materials

The samples of the SKML surveys for external quality control are exempt from CE marking under the IVDR because the result of their measurement is not used in establishing reported patient/client results. In some cases, our sample preparation labs can also provide us with pre-known target control material. The SKML makes such control material available to its participants only for the purpose of verifying the correct calibration of measurement methods. When restricted to this application, no IVDR CE marking of these materials is required. The SKML advises users of these materials that use of these materials without CE marking under the IVDR is not permitted in the establishment or assessment of patient/client results. It is the responsibility of the participants to limit the use of the SKML control and broadcasting materials to the intended use described herein. Neither the SKML nor the manufacturer of the materials is responsible or liable for application outside the intended use.

8. Amendment of the agreement and/or scheme

If it becomes apparent during the execution of the agreement that it is necessary, in order to allow its reasonable execution, to amend or supplement the work to be performed, the parties will modify the agreement accordingly in good time and in consultation with one another.

If the amendment of or supplement to the agreement will have financial or qualitative consequences, the SKML will inform the participant accordingly and any such amendment or supplement will not be implemented until the participant has given its approval.

9. Secrecy

The parties are obliged to observe secrecy with regard to all confidential information that they have obtained from one another or from any other source in connection with the agreement between them. Information is deemed to be confidential if this is notified by the other party or if it ensues from the nature of the information. Data concerning samples, results and relating to patients shall be considered as confidential at all times.

10. Intellectual property

The data and products, including measurement data, provided to the SKML by the participants shall remain the property of the participants. Unless otherwise agreed in writing, the aggregated results of the quality control schemes and of test systems evaluations shall remain the property of the SKML. The SKML is therefore free to perform further analyses of and scientific research on the data files, in so far as all results and analyses arising therefrom are processed in anonymous form.

All procedures relating to schemes, samples, reports, statistical processing, recommendations, software, etc. shall remain the property of the SKML.

All documents, such as reports, recommendations, designs, results, samples and modifications to them, software, etc., provided by the SKML are intended to be used solely by the participant and may not be reproduced or published by it without the prior written permission of the SKML.

The SKML reserves the right to use the knowledge that has been increased or accumulated through the performance of the work for other purposes, in so far as no confidential information is thereby disclosed to any third party or the interest of the participant(s) is not thereby harmed.

11. Notice of cancellation

Notice of cancellation of participation in the schemes is only possible if this is received in writing by the SKML before 1 November. Notices of cancellation received before this date mean that from the following year the participant can no longer participate in the scheme to which the notice of cancellation relates. If the notice of cancellation is received after 1 November, the participant shall be liable for payment to the SKML for the following year.

## 12. Termination of the agreement

Any and all amounts owed to the SKML by the participant shall become immediately due and payable in the event of the participant's bankruptcy or if the participant is granted a moratorium on payments.

In that case, the SKML may suspend the further execution of the agreement or terminate the agreement, without prejudice to its right to demand full compensation.

In the event that the SKML is declared bankrupt or is granted a moratorium on payments, the data provided by the participant shall remain the property of the participant.

## 13. Defects; time limit for lodging a complaint

Complaints about the work that has been performed or concerning the results must be notified to the SKML in writing by the participant within 30 days of discovery.

If a complaint is found to be justified, the SKML will seek a solution that is acceptable to both parties in consultation with the participant.

## 14. Prices

The prices used by the SKML are indexed annually on the basis of the price index figures published by the NZa, which will be announced around July.

The SKML reserves the right to make additional adjustments to the prices in derogation from the aforementioned indexation under special circumstances. Possible causes for such derogation include strongly changed numbers of participants, strong changes in material costs, etc. Prices can be adjusted both up and down.

If the price adjustment concerns an increase that is greater than the aforementioned indexation, this will always be communicated no later than 1 October in order to allow participants to stop participation no later than 1 November if desired, in accordance with Article 11 of these general terms and conditions.

## 15. Invoicing

Payment must be made within 30 days of the date of invoice, in a manner to be specified by the SKML in the currency in which the invoice is made out. The participant will be entitled to a proof of registration as soon as the payment has been received by the SKML.

The participant is in default if payment is not received after 30 days have elapsed since the date of invoice; from the moment it is in default, the participant shall be liable for interest at a rate of 1% per month on the amount due and payable, unless the statutory interest rate is higher in which case the participant shall be liable for payment of statutory interest. The SKML is entitled to suspend its obligations in the event the participant is in default. This shall also include the possibility of excluding the participant from participation in schemes.

Payments made by the participant will first be applied to settle all interest payable and costs and secondly to settle invoices that are due and payable and which have been outstanding for the longest period, even though the participant has stated that the payment relates to a later invoice.

## 16. Collection costs

If the participant is in default or fails to perform one or more of its obligations, all reasonable costs for obtaining settlement or fulfilment without further legal process shall be for the participant's account. In addition to the applicable interest, the participant shall then be liable

to pay 15% additional costs on the amounts(s) due, unless the SKML can show that it has incurred higher costs, which were reasonably necessary. In that case, such costs shall also qualify for reimbursement.

#### 17. Liability

If the SKML – for whatever reason and in whatever respect – is liable, such liability shall be limited as follows:

- The SKML's liability, in so far as this is covered by its liability insurance (where it has such insurance), is limited to the amount of the payment made by the insurer. The SKML will ensure it has liability insurance providing reasonable cover;
- If the insurance (should it exist) does not pay out in any specific case or the loss and/or damage is not covered by the insurance, the SKML's liability shall be limited to twice the invoice value of the assignment, or at least that part of the assignment to which the liability relates;
- The limitations of liability included in these terms and conditions are not applicable in the event that the loss and/or damage is attributable to wilful misconduct or gross negligence committed by the SKML or any persons under its control;
- The SKML shall never be liable for consequential loss or damage;
- The SKML is not liable for any loss and/or damage, of whatever nature, if the SKML has proceeded on the basis of inaccurate and/or incomplete data provided by the participant, unless it ought to have been aware of such inaccuracy or incompleteness.

#### 18. Force majeure

In these General Terms and Conditions, force majeure is understood to mean, in addition to what is defined and understood in that regard in law and case law, all external causes, whether foreseen or unforeseen, over which the SKML is unable to exercise any control, but which nonetheless result in the SKML being unable to fulfil its obligations. This also includes strikes or industrial action in the SKML's company or that of any third party engaged by it.

The SKML may invoke force majeure if the circumstance or situation preventing (further) fulfilment occurs after the SKML ought to have fulfilled its obligation.

The SKML's obligations shall be suspended during a circumstance of force majeure. If the period during which the SKML is unable to fulfil its obligations due to force majeure lasts for more than 2 months, both parties shall be entitled to terminate the agreement without any obligation to provide compensation or to make any return payment arising or existing in such case.

#### 19. Applicable law and choice of forum

Every agreement between the SKML and the participant shall be governed by and construed in accordance with Dutch law.

Situations that are not provided for by these regulations will be decided by the Board of the SKML, after having heard the parties.

The court in the place where the SKML has its registered office has exclusive jurisdiction to hear any dispute. The SKML nevertheless has the right to summon its counterparty to appear before the court that has jurisdiction in accordance with the law.

If these General Terms and Conditions are issued in a language other than Dutch, their interpretation according to Dutch will be guiding in cases of doubt or uncertainty.

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