

## **General Terms and Conditions of Business of the Foundation for Pathobiochemistry and Molecular Diagnostics (Stiftung für Pathobiochemie und Molekulare Diagnostik) for Participation in Surveys of the Reference Institute for Bioanalytics (Referenzinstitut für Bioanalytik) for Surveys from 1 January 2024**

### **I Legal conditions**

- 1 The Reference Institute for Bioanalytics (RfB) is a special-purpose enterprise of the non-profit Foundation for Pathobiochemistry and Molecular Diagnostics (hereinafter: “**SPMD**”) and also conducts surveys for external quality assessment for laboratory medicine testing.
- 2 Through the RfB, the SPMD carries out surveys in accordance with the applicable guidelines of the German Medical Association and/or in analogous application of these guidelines.
- 3 Any contract regarding participation in the surveys is therefore concluded exclusively with the SPMD. The following terms and conditions shall expressly and exclusively apply.
- 4 Various aspects of a survey and/or entire surveys may be subcontracted on the part of the SPMD. In the event of subcontracting, the subcontractors involved in the execution shall be bound by instruction and obligated to maintain confidentiality.

### **II Eligibility requirements**

- 1 Only those who conduct laboratory testing in the exercise of their commercial or self-employed activity can be participants in the surveys, i.e. contractual partners of the SPMD (hereinafter: the “**Participant(s)**”).
- 2 In order to participate, the Participant must first register via the online platform provided and, where required by the SPMD, furnish proof of the aforementioned eligibility.
- 3 The Participant will receive confirmation of registration and will be assigned a unique participant number.
- 4 The Participant must always keep its data – in particular email address, delivery, invoicing and certification address – up to date. Expenses incurred by the SPMD that are

attributable to the outdated data of the Participant may be additionally invoiced to the Participant.

- 5 If a handling permit for infectious material is required, the Participant is responsible for providing such.

### III Conclusion of the contract

- 1 Once registration confirmation is issued to the Participant and the Participant has access data for its account, the Participant can use this to register for one or several surveys. In doing so, the Participant consents to the conclusion of a contract for the execution of surveys under these terms and conditions. The presentation of the surveys on the online platform does not constitute a legally binding offer, but rather merely an invitation to order.
- 2 By sending the complete and truthful online registration through clicking on the button "register/order with obligation to pay", a legally binding registration/order for the sample material and participation in one or several surveys is submitted.
- 3 SPMD will immediately confirm receipt of the submitted registration/order by email (hereinafter: "**order confirmation**"). However, this does not constitute a contract. The Participant must check the correctness of the order confirmation and immediately make any amendments or correct any inaccurate information in the web portal. The Participant can also print out the order confirmation if required.
- 4 The contract for the respective survey is concluded when SPMD accepts the Participant's order for the respective survey ("acceptance"). The contract is accepted through confirmation of order by SPMD or through actual dispatch of the survey. Participants from other European countries are exempt from German VAT if they provide their EU VAT ID, insofar as they are obliged to pay this tax.
- 5 In principle, deviating terms and conditions of a Participant are not recognised.
- 6 If the Participant participates in a transformation or restructuring measure without (partial) universal succession (e.g. company purchase agreement in so-called "asset deal" form), the Participant must ensure that the transfer of the contract concluded in accordance with these terms and conditions to the new legal entity is guaranteed, if and to the extent that the Participant itself will no longer be able to comply with its obligations under this contract. Any necessary cooperation on the part of SPMD is guaranteed.

#### IV **Content of the contract/description of performance**

- 1 Object of the contract is the provision by SPMD of the sample material required for executing the survey or the provision of access to digital images (hereinafter referred to collectively as “test material”) to the Participant, the subsequent feedback of the test results by the Participant and the final collection and evaluation of the data received by SPMD.
- 2 SPMD communicates the result of this evaluation to the submitting Participant and issues it a certificate of participation in the survey. The Participant will receive an additional certificate from SPMD if the evaluation criteria are successfully complied with.
- 3 Participation in surveys is possible in the following variants:

Variant A: open-ended participation in one or several surveys in the context of a long-term commitment (subscription model). These terms and conditions apply for the entire duration of the subscription.

Variant B: participation in individual surveys limited to the duration of the calendar year in which the surveys ordered by the Participant are conducted. These terms and conditions also apply in this respect. In the case of participation according to Variant B after the end of the calendar year, the then applicable conditions shall be taken as the basis for the new conclusion of contract.

- 4 The Participant selects between Variants A and B in the context of its registration for the surveys. Switching between variants is possible at any time up to the registration deadline for the respective survey.
- 5 The Participant shall receive an annual schedule with the relevant deadlines and dates for the surveys (registration dates for participation, dates for sending or provision of the survey samples/materials and last submission date for the results) before the beginning of each calendar year or immediately after registration, when this occurs mid-way through a year. The deadlines and dates listed in the schedule are binding for the Participant. Late registration does not constitute entitlement to participate in the survey. The Participant shall bear any expenses associated with its cooperation obligations in the context of its participation in the survey (e.g. submission of results), which it was late to execute. SPMD is entitled to cancel the survey before commencement or to postpone it to a reasonable extent, if there are reasons that would make execution impossible (e.g. if samples are not available). SPMD will inform the Participants about this and make every effort to offer a timely alternative date for the execution of the survey.

- 6 The schedule of deadlines and dates also includes the prices to be paid to SPMD for participation in the respective survey.
- 7 These prices are binding for the Participant. All prices are net and do not include the applicable statutory VAT.
- 8 Samples are sent out ex works (Incoterms 2023) via a transport company designated by SPMD on the dates and at the costs specified on the website. Risk of loss or damage is transferred to the Participant upon handover of the samples to the transport company. The Participant shall inform SPMD immediately if it does not receive the samples within one day of the respective shipping date. Transport costs, taxes and customs shall be borne by the Participant. The Participant is responsible for any import permits required. Any costs for return transport or the destruction of samples due to the lack of import permits or refusal of acceptance shall be borne by the Participant. Digital images will be made available to Participants online. Participants will be provided with online access to data transmission. Invoicing by SPMD will be carried out after completion of the respective survey. The Participant is required to check the invoice. If no objections are raised within a period of 1 month after receipt, the invoice shall be deemed to have been approved. Payments from Participants in Germany can be made only by bank transfer or direct debit. Payments from Participants outside Germany can be made only by bank transfer. Invoices can be sent by post or email, at SPMD's discretion. The Participant agrees that it will receive electronic-format invoices to the email address provided by it in the context of registration. The Participant also undertakes to create and maintain the technical requirements for the proper receipt and opening of the email and its attachment. Should the Participant have technical problems with the receipt or opening of the electronically attached invoice, it must inform SPMD/RfB about this without delay. If the email address provided by the Participant no longer exists, it must immediately inform SPMD/RfB about this. The Participant can revoke its consent to the sending of invoices by email at any time. The posting of invoices in web portals is rejected.

## **V Execution of the surveys**

- 1 For both Variant A and B, the Participant shall receive all surveys selected by it during registration at the respectively announced survey period for the entire duration of the contractual period.
- 2 The Participant carries out the examination of the material provided and transmits the results and the information required for the evaluation online.

- 3 SPMD may refuse to participate in surveys and to issue certification if the Participant is in default with its payment obligations. The obligation to pay arises at the time of conclusion of contract in accordance with Section III(4) of these General Terms and Conditions of Business. It expires only in the event of payment by the Participant in these General Terms and Conditions of Business or cancellation of the survey by SPMD in accordance with Section IV(5) of these General Terms and Conditions of Business or in the event of timely cancellation by the Participant within the period specified in the confirmation of registration.

## **VI Evaluation of the surveys**

- 1 SPMD evaluates the test results determined by the Participant in the context of the survey, provided that they are transmitted to SPMD in due time in accordance with the schedule. The Participant is not entitled to the evaluation of test results received late by SPMD.
- 2 Participants submit test results only online. Evaluation by SPMD is based on evaluation criteria defined by SPMD/RfB. Where available, the criteria defined from the relevant tables in the Guidelines of the German Medical Association for Quality Assurance of Laboratory Medical Examinations (RiliBÄK) in the currently valid version shall be applied.
- 3 The Participant receives a certificate of participation in the survey for all measurands/tests submitted. In addition, the Participant receives a certificate listing all measurands whose parameters/test results concur with the targets. Date of issue corresponds to the concluding date of the respective survey. In the event that the RiliBÄK is applied, the term of validity of the certificates is regulated by those guidelines and applies as of the date of issue. The Participant can freely use its evaluations and reports within the scope of the intended use.

## **VII Rescission, termination**

- 1 The Participant is free to withdraw from participation in a survey up until the end of registration as specified in the schedule. Withdrawal is no longer possible after the end of registration.
- 2 If a Participant has registered to participate in several surveys, it is possible to withdraw from participation in all or only individual surveys, but only up to the date specified in Section VII (1) sentence 2.
- 3 Participants with contract type A may terminate the subscription at any time. From the date of termination, only those surveys for which registration had already concluded as of that date will be delivered. It is also possible to suspend the subscription for an agreed

period of time for one or all registered surveys, up to the respective registration deadline.

- 4 Irrespective of the type of contract, rescission and/or termination must be undertaken online via the Participant account or by email with reference to the Participant's registration number. There are no special requirements regarding form.

### **VIII Complaints/liability**

- 1 A complaint is only possible within a period of 4 weeks after receipt of the survey results. After expiry of this period, claims of the Participant due to complaint are excluded.
- 2 In the event of a justified complaint for which SPMD is responsible, either no invoice will be issued or a replacement survey will be carried out. The right to choose lies with SPMD. Any costs incurred for reagents, time, etc. cannot be reimbursed unless SPMD is liable under this Section VIII(3) and (4).
- 3 SPMD shall only be liable for damages of any kind – where the other eligibility requirements are met – in the event of intent and gross negligence as well as in the event of a breach of essential contractual obligations by SPMD, legal representatives or vicarious agents as well as in the absence of warranted properties. In all other respects, liability for damages of any kind, regardless of the basis of the claim, including liability for fault at the time of conclusion of the contract, is excluded.
- 4 None of the above limitations of liability apply to the liability of SPMD, a legal representative or vicarious agent for guaranteed characteristics, due to injury to life, limb or health, or under the Product Liability Act.

## **IX Confidentiality/data privacy**

- 1 SPMD is obliged to label data relevant to the order and store it in a way that makes it trackable. For this purpose, the data and information are, for example, recorded in a database system and stored for 10 years.
- 2 SPMD is expressly entitled to use data collected in the course of the provision of services in an anonymous manner for its own purposes, e.g. for statistical surveys or technical evaluations and analysis.
- 3 The customer can object to the use of the data in accordance with No. 3 of this Section IX at any time or revoke their consent in writing.
- 4 Notwithstanding the foregoing provision, SPMD and the customer undertake to comply with European regulation (EU) 2016/679 (GDPR) as amended. Further information can be found at <https://www.rfb.bio/cgi?page=Impressum#privacy>.
- 5 SPMD and the customer mutually undertake to treat confidentially all business and personal data, business and trade secrets of the other party that become known in the course of the contractual activity. The transfer of confidential information does not create any ownership, patent or licensing rights of one contractual partner to the confidential information of the other contractual partner.
- 6 The data that must be treated confidentially includes, in particular, trade secrets / information within the meaning of Art. 2 para. 1 of Directive (EU) 2016/943 “on the protection of confidential know-how and confidential business information” or Section 2(1) of the Act on the Protection of Trade Secrets (GeschGehG).
- 7 The duty of confidentiality does not extend to:
  - information that demonstrably originates in generally accessible sources,
  - information that is already in the public domain or is generally known, or corresponds to the current state of the art
  - information that the respective party is obligated to disclose due to legal provisions / official orders (e.g. requests for information from courts and authorities),
  - inspections of order documentation by assessors of the accreditation body,
  - SPMD documents that are subject to publication requirements and are created for the customer (e.g. certificates),
  - reports to an arbitration board in the case of a complaint.
- 8 The obligation of confidentiality ends 3 years after the completion of the order / end of the contractual cooperation with the customer, unless otherwise agreed with the customer.

**X Applicable law, place of jurisdiction**

- 1 The contract concluded between the Participant and SPMD is subject to the law of the Federal Republic of Germany, subject to mandatory international private law regulations on the basis of an agreement between the participating parties.
- 2 To the extent permissible, the courts in Bonn shall have exclusive jurisdiction for all disputes arising from or in connection with the relevant contractual relationship. The place of performance for all obligations arising from the contract is Bonn, Germany.