Stiftung für Pathobiochemie und Molekulare Diagnostik |
Referenzinstitut für Bioanalytik | Friesdorfer Str. 153, 53175 Bonn

Vorstand
Gunther Schabio

Leitung des RfB
Dr. Anja Kessler

General Terms and Conditions of the

Foundation for Pathobiochemistry and Molecular Diagnostics for participation in proficiency tests of the Reference Institute for Bioanalytics for proficiency tests

from 01.01.2025 (AGB)

I. Legal situation

1. The Reference Institute for Bioanalytics (RfB) is a special-purpose organisation of the non-profit Foundation for Pathobiochemistry and Molecular Diagnostics (hereinafter "**SPMD**") and also carries out proficiency testing for external quality control for laboratory medical examinations as an accredited proficiency testing provider according to DIN EN ISO/IEC 17043 within the scope of the accreditation scope and as a reference institute listed with the German Medical Association.

2. A contract for participation in the round robin tests is therefore concluded exclusively with SPMD. These General Terms and Conditions apply expressly and exclusively.

3. Various aspects of a proficiency test and/or entire proficiency tests can be subcontracted by SPMD. In the case of subcontracting, the work is carried out by subcontractors who are bound by instructions and obliged to maintain confidentiality.

II. Participation requirements

1. Only an entrepreneur can be a participant in the round robin tests, i.e. a contractual partner of SPMD. For the purposes of these GTC, an "entrepreneur" is a natural or legal person or a partnership with legal capacity who, when concluding the contract with SPMD, is acting in the predominant exercise of their commercial or independent professional activity (Section 14 (1) BGB), who carries out laboratory tests in the exercise of their commercial or independent activity (hereinafter "the participant(s)").

2. In order to participate, the participant must first register via the online platform provided for this purpose and, if required by the SPMD, provide proof of the aforementioned participation requirements.

3. The participant receives a registration confirmation and is assigned a unique participant number.

4. The participant must keep his/her data, in particular e-mail address, delivery address, billing address and certificate address, up to date at all times. Expenses incurred by SPMD due to the participant's data not being up to date may be charged to the participant additionally.

5. When participating in the SPMD EQA schemes, the requirements of the current guideline of the German Medical Association for the quality assurance of laboratory medical examinations (Rili-BÄK) or a related guideline are observed. By registering for an EQA scheme, the participant expressly recognises the corresponding validity. By participating in the SPMD's offers, the participant assures that the processing of the EQA schemes will be carried out by the participant and not by third parties.

6. Furthermore, by registering for an EQA scheme, the participant confirms that, in the case of participation in EQA schemes with infectious material (material with pathogens), he/she either has a licence from the competent authority in accordance with Section 44 IfSG (Infection Protection Act) or has been officially exempted by this authority. The participant is aware that this is also a very important contractual obligation.
   Participants from abroad must observe the respective national legal regulations that apply to the handling of infectious material.
7. Samples and materials from the proficiency test may not be passed on to third parties.
8. Third parties within the meaning of these conditions of participation are persons who are outside the legal relationship between SPMD and the contractual partner within the meaning of II. Section 1.

III. Conclusion of the contract

1. The participant can only register for one or more EQA schemes once registration has been confirmed for the participant and the participant has been provided with access data for his/her account. By doing so, the participant agrees to the conclusion of a contract for the performance of proficiency tests in accordance with these GTC. The presentation of the EQA schemes on the online platform does not constitute a legally binding offer, but merely an invitation to place an order.
2. By submitting the online registration form, which must be completed in full and truthfully, by clicking on the "Register/order with obligation to pay" button, a legally binding registration or order for the trial material and participation in one or more ring trials is submitted.
3. SPMD will immediately confirm receipt of the submitted registration/order by e-mail (hereinafter "**order confirmation**"). However, this does not yet constitute a contract. The participant must check the order confirmation for accuracy and correct any changes or incorrect information immediately via the web portal. The participant can also print out the order confirmation if required.
4. The contract for the respective EQA scheme is concluded when SPMD accepts the participant's order for the respective EQA scheme ("acceptance"). Acceptance of the contract is effected by an order confirmation from SPMD or by the actual despatch of the EQA scheme.
5. Participants from other European countries are exempt from German VAT if they provide their EU VAT ID, insofar as they are obliged to pay VAT.
6. Deviating terms and conditions of a participant are not recognised.
7. If the Participant takes part in a reorganisation or restructuring measure without (partial) universal succession (e.g. company purchase agreement in the form of an asset deal), the Participant must ensure that the contract concluded in accordance with these GTC is transferred to the new legal entity if and to the extent that the Participant is no longer able to fulfil its obligations under this contract. Any necessary co-operation by SPMD is guaranteed.

IV. Content of the contract/service description

1. The object of the contract is the provision by SPMD of the sample material required for the performance of the EQA scheme or the facilitation of access to digital images (hereinafter jointly referred to 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. The sample material must be treated by the participant in the same way as patient samples. The participant undertakes to ensure that the safety instructions for the EQA schemes and the relevant legal requirements and professional duties of care for the handling of samples are observed. The sample material provided may only be used for proficiency testing purposes and - in the event of problems with certain in vitro diagnostics ("IVD") - for the purpose of testing IVD. Samples may not be used for purposes other than those for which they were intended; in particular, they may not be used to produce pathogens or pathogen components for scientific or commercial purposes. Samples must be disposed of properly.
3. The SPMD informs the submitting participant of the result of this evaluation and issues a certificate of participation in the EQA scheme. If the evaluation criteria are successfully met, the SPMD will also issue the participant with a certificate.
4. Participation in round robin tests is possible in the following variants:
   Variant A: unlimited participation in one or more proficiency tests as part of a continuing obligation (subscription model). The current GTC apply for the entire duration of the subscription.

   Variant B: Participation in individual proficiency tests limited to the duration of a calendar year in which the proficiency tests ordered by the participant are carried out. In this respect, the respective valid GTC also apply. In the event of participation in accordance with variant B after the end of the calendar year, the then applicable GTC shall form the basis for the new conclusion of the contract.

   The participant will be informed of any changes to the GTC.
5. The participant chooses between variant A and variant B when registering for the EQA scheme. It is possible to switch between the variants at any time up to the registration deadline for the respective EQA scheme.
6. The participant can receive an overview of the planned EQA schemes and the relevant deadlines and dates (e.g. registration dates for participation, dates for dispatch or provision of the EQA samples/materials and last day for submission of the results) for the EQA schemes (hereinafter referred to as the programme) before the start of each new calendar year. In any case, the current version of this programme is available online at www.rfb.bio. This also applies if a participant registers during the year. The deadlines and dates listed there are binding for the participant. Late registration, i.e. after the respective registration deadline for an EQA scheme, does not entitle the participant to take part in the EQA scheme. Any obligations to co-operate on the part of the participant within the scope of his/her participation in the EQA scheme (e.g. entry of results) that the participant undertakes late shall be borne by the participant. The SPMD is entitled to cancel the EQA scheme before it begins or to postpone it within reasonable limits if there are reasons that make it impossible to carry it out (e.g. if samples are not available). The SPMD will inform the participant of this and endeavour to offer an alternative date for carrying out the EQA scheme as soon as possible. However, the participant's order remains binding as long as SPMD does not definitively cancel an EQA scheme.
7. This programme also lists the prices to be paid to the SPMD for participation in the respective EQA scheme, including the prices for additional sample material. If the participant is given the opportunity to have several analytes evaluated, additional costs for the number of analytes defined in the programme in the form of graduated prices may arise in addition to the basic price. These and also an overview of the current delivery costs per country are listed separately on the website www.rfb.bio.

8. The prices are binding for the participants. All prices are net prices and do not include the respective statutory VAT.
9. Samples are shipped ex works (Incoterms®2020) via a transport company designated by SPMD on the dates specified on the website. The participant bears the transport costs, taxes and customs duties. The transport costs are published on the SPMD website. The transport costs stated on the website www.rfb.bio at the time the contract is concluded shall initially form part of the contract. These are based on a mixed calculation of the various transport service providers and shipping methods used. SPMD reserves the right to adjust these costs if the transport service providers used change their prices. The transport costs valid at the time of the respective sample dispatch (service date) therefore apply. Once the samples have been handed over to the transport company, the risk of loss or damage is transferred to the participant. The participant shall inform SPMD immediately if the samples have not been received by the participant no later than 3 working days (Monday to Friday) after the agreed dispatch date. The participant is responsible for obtaining the necessary import licences. Costs for return transport or destruction of samples due to missing import licences 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 for data transmission. Invoicing by the SPMD takes place after completion of the respective EQA scheme. The participant must check the invoice. If the participant does not raise any objections to the invoice within one month of receipt, it shall be deemed to have been approved. Payments by participants from Germany can only be made by bank transfer or direct debit. Payments from participants outside Germany can only be made by bank transfer . At the discretion of SPMD, invoices may be sent by post or e-mail. The participant agrees to receive invoices in electronic form to the e-mail address provided by him/her as part of his/her registration. The participant also undertakes to create and maintain the technical requirements for the proper receipt and opening of the e-mail and its attachment. If the participant has technical problems receiving or opening the electronically attached invoice, he/she must inform the SPMD/the RfB of this immediately. If the e-mail address provided by the participant no longer exists, the participant must inform SPMD/the RfB immediately. The participant may revoke his/her consent to the sending of invoices by e-mail at any time. The posting of invoices on web portals is rejected.

V. Carrying out the round robin tests

1. In the case of contract type A and contract type B, the participant receives all the EQA schemes selected by him/her during the registration process for the announced EQA scheme period for the entire duration of the contract period.
2. The participant carries out the analysis of the material provided and transmits the results and the information required for the evaluation online. By submitting the results, the participant confirms that only the results of the quantitative interlaboratory tests that have actually been carried out by the participant in relation to the sample material provided and under his responsibility will be submitted.
3. SPMD may refuse participation in proficiency tests and the delivery of certificates if the participant is in arrears with its payment obligations. SPMD is also authorised to refuse to deliver certificates for as long as there are reasonable grounds for suspecting a breach of the obligation under V section 2.
4. The payment obligation arises at the time of conclusion of the contract in accordance with Section III No. 4 of these GTC. It shall only expire in the event of payment by the participant of these GTC or cancellation of the round robin test by SPMD in accordance with Section IV No. 5

of these GTC or in the event of timely cancellation by the participant within the period specified in the registration confirmation.

VI. Evaluation of the interlaboratory tests

1. The SPMD evaluates the test results determined by the participant as part of the EQA scheme, provided that these are submitted to the SPMD on time in accordance with the schedule. The participant has no claim to evaluation for test results received late by the SPMD.
2. The participant enters the test results exclusively online via the RfB online platform. The evaluation by the SPMD is based on evaluation criteria defined by the SPMD/RfB. Where available, the criteria set out in the relevant tables in the current version of the German Medical Association's guideline on quality assurance for laboratory medical examinations (RiliBÄK) are applied.
3. The participant receives a certificate of participation in the round robin test for all measurement/test results submitted. In addition, the participant receives a certificate in which all measured variables whose measurement/test results correspond to the target specifications are listed. The date of issue corresponds to the closing date of the respective EQA scheme. If the RiliBÄK is applied, the validity period of the certificates is regulated by the RiliBÄK and applies from the date of issue. If there are changes due to changes in the framework conditions (e.g. the basis of the target value has actually changed due to the participant collective), the SPMD is authorised to issue revision certificates, which means that the certificates originally issued lose their validity.
4. The participant may freely dispose of his analyses and reports within the scope of the intended use.

VII. Withdrawal, cancellation

1. The participant is free to withdraw from participation in an EQA scheme up to the registration deadline stated in the schedule. Cancellation is not possible after the registration deadline.
2. If a participant has registered to take part in several EQA schemes, it is possible to withdraw from participation in all or only individual EQA schemes. However, this can only be done up to the time specified in VII. clause 1 sentence 2.
3. Participants with contract type A can cancel their subscription at any time. From the time of cancellation, only the EQA schemes for which the registration period had already expired at that time will be delivered. It is also possible to suspend the subscription for an agreed period of time for one or all registered EQA schemes until the respective registration deadline.
4. Irrespective of the type of contract, cancellation and/or termination must be made online via the participant account or by e-mail with reference to the participant registration number. There are no special formal requirements.

VIII. Complaints/liability

1. After receipt of the proficiency test results, a complaint is only possible within a period of 4 weeks. After expiry of this period, claims by the participant due to a complaint are excluded.
2. In the event of a justified complaint for which SPMD is responsible, either the invoice will not be issued or a replacement ring test will be carried out. SPMD has the right to choose. The costs incurred for reagents, time, etc. cannot be reimbursed unless SPMD is liable in accordance with this Section VIII, Clauses 3 to 5.
3. SPMD shall only be liable for damages of any kind - if the other conditions for a claim are met - in the event of intent and gross negligence and in the event of a breach of material contractual obligations by SPMD, legal representatives or vicarious agents and in the absence of warranted

characteristics. Otherwise, liability for damages of any kind, regardless of the basis of the claim, in particular also for claims for damages arising from unauthorised action (e.g. so-called "further damage"), including liability for culpa in contrahendo, is excluded.

4. None of the above limitations of liability apply to liability for guaranteed characteristics, for injury to life, limb or health or under the Product Liability Act by SPMD, a legal representative or vicarious agent.
5. SPMD's liability is limited to EUR 25,000. If the customer is of the opinion that the maximum liability amount does not cover the foreseeable damage typical for the contract, he must notify SPMD of this when placing the order. In this case, the parties shall agree on an appropriate maximum liability limit. The maximum liability sum in accordance with sentence 1 does not apply to wilful or grossly negligent behaviour on the part of SPMD or its executive employees. In the event of wilful or grossly negligent behaviour on the part of SPMD's vicarious agents, the maximum liability amount pursuant to sentence 1 shall not apply in the event of a breach of cardinal obligations. Furthermore, the maximum liability amount in accordance with sentence 1 does not apply in the cases of extended liability listed in paragraph 5. By way of derogation from this, the maximum liability sum expressly applies in the event of a breach of cardinal obligations in the event of simple/slight negligence, unless another of the cases of extended liability listed in paragraph 5 applies at the same time.

IX. Confidentiality/data protection

1. SPMD is obliged to label order-related data and store it in a traceable manner. To this end, the data and information is recorded in a database system and stored for 10 years.
2. SPMD is expressly entitled to use anonymised data collected in the course of providing the service for its own purposes, e.g. for statistical surveys or technical evaluations and assessments.
3. The customer may object to the use of the data in accordance with No. 3 of this Section IX at any time or revoke consent in writing.
4. Notwithstanding the above provisions, SPMD and the customer undertake to comply with the European Regulation (EU) 2016/679 (General Data Protection Regulation) as amended. Further information on data protection can be found at https://www.rfb.bio/cgi?page=Impressum#privacy.
5. SPMD and the customer mutually undertake to treat as confidential 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 establish any ownership, patent or licence rights of one contracting party to the confidential information of the other contracting party.
6. The data that must be treated confidentially includes, in particular, business secrets / information within the meaning of Art. 2 No. 1 of Directive (EU) 2016/943 "on the protection of confidential know-how and confidential business information" or Section 2 No. 1 of the German Trade Secrets Protection Act (GeschGehG).
7. The obligation of confidentiality does not apply to:
    - Information that can be proven to originate from generally accessible sources,
    - Information that is already in the public domain or generally known or corresponds to the current state of the art
    - Information that the respective party is obliged to disclose due to legal provisions / official orders (e.g. requests for information from courts and authorities),
    - The inspection of order documents by assessors of the accreditation body,

- SPMD documents (e.g. certificates) created for the customer that are subject to publication,
- reporting to an arbitration board in the event of a complaint.

8. The obligation of confidentiality ends 3 years after completion of the order / end of the contractual co-operation with the customer, unless otherwise agreed with the customer.

X. Delivery stop, blocking

1. SPMD is authorised to block the account and delivery of the examination material/certificates in the event of an uncovered account and payment arrears after an unsuccessful reminder.
2. The same applies if the participant breaches material obligations under this contract.
3. SPMD is also entitled to block any access authorisation that has been created using false or fictitious data.

XI. Changes to the GTC and price adjustment

1. The GTC may be amended insofar as this is necessary to adapt to developments that were not foreseeable when the contract was concluded and which SPMD did not cause or cannot influence and whose non-observance would disturb the balance of the contractual relationship to a not insignificant extent and insofar as this does not affect essential provisions of the contractual relationship. Material provisions are those relating to the type and scope of the contractually agreed services and the term, including the provisions on cancellation.
2. Furthermore, the GTC may be amended insofar as this is necessary to eliminate not insignificant difficulties in the fulfilment of the contract due to loopholes that have arisen after the conclusion of the contract. This may be the case in particular if the case law on the validity of provisions of these GTC changes, if one or more provisions of these GTC are declared invalid by the courts or if a change in the law leads to the invalidity of one or more provisions of these GTC.
3. In the case of continuing obligations or participation already ordered by the participant, SPMD may adjust the prices to be paid at its reasonable discretion in line with the development of the costs that are decisive for the price calculation. A price increase is possible and a price reduction must be made if, for example, the costs for the production and provision of the products (e.g. purchasing costs, transport costs) increase or decrease or other changes in the technical or legal framework conditions lead to a changed cost situation (e.g. increased regulatory effort, changed legislation for proficiency testing providers or in the field of in-vitro diagnostics and medical devices). Increases in one type of cost, e.g. infrastructure costs, may only be used for a price increase to the extent that they are not offset by any declining costs in other areas (e.g. price reductions in the area of infrastructure). In the event of cost reductions, SPMD shall reduce prices to the extent that these cost reductions are not fully or partially offset by increases in other areas. In exercising its reasonable discretion, SPMD shall select the respective points in time of a price change in such a way that cost reductions are not taken into account according to standards that are less favourable to the customer than cost increases. Price changes in accordance with this section are only possible on the first day of the month. SPMD will notify the customer of the change in text form at least six weeks before the planned effective date. In the event of a price change, the customer has the right to cancel the respective order placed as part of participation in a round robin test in text form without observing a cancellation period at the time the change comes into effect. SPMD shall inform the customer of this separately in the price change notification. In the event of cancellation, the price change shall not take effect vis-à-vis the customer. Otherwise, Section 315 BGB remains unaffected.

4. Irrespective of the aforementioned provisions of the clauses, SPMD is entitled in the event of an increase in the statutory value added tax and obliged in the event of a reduction to adjust the prices accordingly at the time of the respective change, without this giving the customer a right of cancellation.

XII. Applicable law, place of jurisdiction and severability clause

1. The contract concluded between the participant and the SPMD is subject to the law of the Federal Republic of Germany, subject to mandatory international, private-law provisions by agreement of the parties involved.
2. If the participant is a merchant within the meaning of Section 1 (1) of the German Commercial Code, a legal entity (under public law) or a special fund under public law, the place of jurisdiction for all disputes arising from or in connection with the contract shall be Düsseldorf. The place of fulfilment for all obligations arising from the contract is Bonn, Germany.
3. Should any provision of the contract be or become invalid or unenforceable in whole or in part, this shall not affect the validity of the remaining provisions of this contract. The same shall apply if and insofar as a loophole is found in this contract. In place of the invalid or unenforceable provision or to fill the gap, an appropriate provision shall apply which, as far as legally possible, comes closest or corresponds to what the contracting parties intended economically or would have intended according to the meaning and purpose of this contract if they had considered this point. This shall also apply if the invalidity of a provision is based, for example, on a scope of performance or time (deadline or date) provided for in this contract; in such cases, a legally permissible measure of performance or time (deadline or date) that comes as close as possible to the intended economic purpose shall take the place of what has been agreed.