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 effective from 01.10.2025 (GTC)

I. Legal Relationships

1. The Reference Institute for Bioanalytics (RfB) is an ancillary operation of the non-profit Foundation for Pathobiochemistry and Molecular Diagnostics (hereinafter "SPMD") and conducts proficiency tests for external quality control of laboratory medical examinations as an accredited proficiency test provider according to DIN EN ISO/IEC 17043 within the scope of accreditation and as a reference institute listed by the German Medical Association.
2. Therefore, a contract for participation in the proficiency tests is concluded exclusively with the SPMD. These GTC apply exclusively and explicitly.
3. Various aspects of a proficiency test and/or entire proficiency tests can be subcontracted by the SPMD. In the event of subcontracting, the performance is carried out by subcontractors who are bound by instructions and committed to confidentiality.

II. Participation Requirements/Obligations of the Participant

1. Participants in the proficiency tests, i.e., contractual partners of the SPMD, can only be entrepreneurs. For the purposes of these GTC, an "entrepreneur" is a natural or legal person or a legal partnership that, at the time of concluding the contract with the SPMD, acts predominantly in the exercise of its commercial or independent professional activity (§ 14 para. 1 BGB) and carries out laboratory examinations in the exercise of its commercial or independent professional activity (hereinafter "the participant(s)").
2. For participation, initial registration of the participant via the provided online platform and, if required by the SPMD, proof of the aforementioned participation requirements are necessary.
3. The participant receives a registration confirmation and is assigned a unique participant number.
4. The participant must keep their data, especially email address, delivery address, billing address, and certificate address, up to date. Any expenses incurred by the SPMD due to outdated participant data may be additionally charged to the participant.
5. In the context of participation in the SPMD's proficiency tests, the provisions of the currently applicable guideline of the German Medical Association for quality assurance of laboratory medical examinations (Rili-BÄK) or a related guideline are observed. By registering for a proficiency test, the participant explicitly acknowledges the compliance by the SPMD.
6. The participant assures that the processing of the proficiency tests is carried out by the participant and not by third parties.
7. The participant further assures that they treat the sample material like patient samples. The participant undertakes to ensure that the safety instructions for the proficiency tests and the relevant legal requirements and professional duties of care regarding the handling of the provided samples are observed. Thus, by registering for a proficiency test, the participant undertakes to have a permit from the competent authority (in Germany according to §44 IfSG) or to

be exempted from this obligation by the supervisory authority in case of participation in proficiency tests with infectious material (material containing pathogens). The participant is aware that this is also a fundamental contractual obligation. Participants from abroad must comply with the respective national legal regulations governing the handling of infectious material.

8. The provided sample material may only be used for proficiency testing purposes and, in the event of problems with certain in-vitro diagnostics ("IVD"), for quality control purposes within the scope of IVD verification. Samples may not be misused, especially not for the production of pathogens or pathogen components for scientific and commercial purposes. Furthermore, the participant is prohibited from performing deconvolution or reverse engineering to attempt to restore or modify the material.
9. Samples must be disposed of properly. Samples and materials from the proficiency test may not be passed on to third parties. Third parties, in this context, are persons who are outside the legal relationship between the SPMD and the contractual partner as per II. Section 1.

III. Conclusion of the Contract

1. Only after a registration confirmation has been issued to the participant and access data for their account has been communicated, the participant can register for one or more proficiency tests. By doing so, the participant agrees to the conclusion of a contract for the conduct of proficiency tests under these GTC. The presentation of the proficiency tests on the online platform constitutes a non-binding offer, merely an invitation to order.
2. By submitting the completely and truthfully filled out online registration by clicking the "Order" button, a legally binding registration or order for the sample material and participation in one or more proficiency tests is made.
3. The SPMD will immediately confirm receipt of the submitted registration/order by email (hereinafter "Order Confirmation"). However, this does not yet constitute a contract. The participant must check the order confirmation for accuracy and immediately correct any changes or incorrect information via the web portal. The participant can also print the order confirmation if needed.
4. The contract for the respective proficiency test is concluded when the SPMD accepts the participant's order for the respective proficiency test ("Acceptance"). The acceptance of the contract is made through an order confirmation from the SPMD or through the actual execution of the shipment of the proficiency test.
5. Participants from European countries are exempt from German VAT upon notification of their EU VAT ID, provided they are obligated to pay it.
6. Deviating terms and conditions of a participant are not recognized.
7. If the participant undergoes a restructuring or transformation measure without (partial) universal succession (e.g., corporate purchase agreement in the form of an "asset deal"), the participant must ensure that the transfer of the contract concluded according to these GTC to the new legal entity is secured, insofar as the participant is no longer able to fulfill their obligations under this contract. Any required cooperation by the SPMD will be ensured.

IV. Content of the Contract/Service Description/Obligations of the Participant

1. The subject of the contract is the granting of participation in the proficiency test conducted by the SPMD under the conditions specified in these GTC. The services of the SPMD include, in particular, the obligation to collect and evaluate data submitted by the participant (hereinafter referred to as the "result evaluation"). The sample material required for the examination by the participant or access to digital images (hereinafter collectively referred to as "examination material") will be provided by the SPMD. Furthermore, the SPMD will provide the participant with the result evaluation regarding their participation.
2. The SPMD communicates the result evaluation to the submitting participant. Upon successful compliance with the evaluation criteria, the participant will additionally be issued a certificate by the SPMD. The SPMD can also issue the participant a certificate of participation in the respective proficiency test. Further details are contained in Section VI.
3. Participation in proficiency tests is possible in the following variants:
    - Variant A: Unlimited participation in one or more proficiency tests within the framework of a continuing obligation (subscription model). The currently applicable 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 conducted. The respective valid GTC also apply in this case. If participation occurs according to Variant B after the end of the calendar year, the then applicable GTC will form the basis of the new contract conclusion.
4. The participant chooses between Variant A and Variant B when registering for the proficiency tests. It is possible to switch between the variants at any time until the registration deadline for the respective proficiency test.
5. An overview of the planned proficiency tests and the relevant deadlines and dates (e.g., registration deadlines for participation, dates for shipping or provision of proficiency test samples/materials, and the last submission date for results) for the proficiency tests (hereinafter referred to as the "Program") can be obtained by the participant before the start of each new calendar year. In any case, this program is available online in the current version at www.rfb.bio . This also applies in the case of mid-year registration of a participant. The deadlines and dates listed there are binding for the participant. Late registration, i.e., after the respective registration deadline for a proficiency test, does not entitle participation in the proficiency test. Any obligations of the participant in the context of their participation in the proficiency test (e.g., entry of results) that are fulfilled late are at the participant's expense. The SPMD is entitled to cancel or postpone the proficiency test within a reasonable scope before its commencement if there are reasons that make its execution impossible (e.g., if samples are not available). The SPMD will inform the participant about this and endeavor to offer an alternative date for the proficiency test as soon as possible. The participant's order remains binding until there is a definitive cancellation of a proficiency test by the SPMD.
6. This program also additionally lists the prices to be paid to the SPMD for participation in the respective proficiency test, including the prices for additional sample material. If the participant is given the opportunity to evaluate multiple analytes, additional costs may arise in the form of tiered prices, in addition to the base price, for the number of analytes defined in the

program. An overview of the current shipping costs per country is also separately listed on the website www.rfb.bio .

7. The prices are binding for the participants. All prices are net prices and are subject to the applicable statutory value-added tax.
8. The shipment of the samples is made ex-works (Incoterms®2020) via a transport company specified by the SPMD at the dates set on the website. The participant bears the transport costs, taxes, and duties. The transport costs are published on the SPMD website. The transport costs specified on the website www.rfb.bio at the time of the conclusion of the contract initially become part of the contract. These are based on a mixed calculation of the various transport service providers and shipping methods used. The SPMD reserves the right to adjust these costs if the transport service providers used change their prices. Therefore, the transport costs valid at the time of the respective sample shipment (performance date) apply. After the handover of the samples to the transport company, the risk of loss or damage passes to the participant. The participant must immediately inform the SPMD if the samples have not been received by the specified delivery date (within 3 working days (Monday to Friday) after the set delivery date). The participant is responsible for obtaining the necessary import permits. Costs for return transport or destruction of samples due to lack of import permits or refusal of acceptance are borne by the participant. Digital images are made available to the participants online. Participants are provided with online access to data transmission.
9. Invoicing by the SPMD is done after the completion of the respective proficiency test. The participant must check the invoice. If the participant does not raise any objections to the invoice within one month of receipt, it is deemed approved. Payments from participants in Germany can only be made by bank transfer or direct debit. Payments from participants outside Germany can only be made by digital payment methods. At the SPMD's discretion, invoices can be sent by mail or email. The participant agrees to receive invoices in electronic form at the email address provided during registration. The participant is also obligated to create and maintain the technical conditions for the proper receipt and opening of the email and its attachment. If the participant has technical problems receiving or opening the electronically attached invoice, they must immediately inform the SPMD/RfB. If the email address provided by the participant is no longer valid, the participant must immediately inform the SPMD/RfB. The participant can revoke their consent to receiving invoices by email at any time. The posting of invoices in customer web portals is rejected.
10. The participant must provide a valid and receivable email address for both invoices and reminders during registration and keep it up to date. Reminders from the SPMD are generally sent by email to the address provided by the participant during registration. Changes to the email address must be immediately communicated to the SPMD.
11. Notifications from the SPMD are deemed received once they have been sent to the email address last provided by the participant and are retrievable under normal circumstances. The participant bears the burden of proof if a delivery confirmation stored by the SPMD does not lead to receipt in their sphere. If an invoice or reminder cannot be delivered due to an email address not updated or not functional by the participant, the participant bears the resulting delays and consequences. If the delivery of an invoice/reminder is requested by the

participant or due to a missing or non-functional email address by mail, the SPMD is entitled to charge an additional processing and shipping fee of 5.00 euros (net) per invoice/reminder to the participant. This fee will be invoiced separately to the participant. The participant reserves the right to prove that the SPMD incurred lesser or no expenses.

V. Conduct of the round robin tests

1. For both contract type A and contract type B, the participant receives all proficiency tests selected during registration for the respective announced proficiency test period for the entire duration of the contract.
2. The participant conducts the examination of the provided material and submits the results and the information required for the evaluation online. By submitting the results, the participant confirms that only the results actually obtained through the examination of the participant based on the submitted sample material and under their responsibility have been submitted for the proficiency tests.
3. The SPMD can refuse participation in proficiency tests and the issuance of certificates if the participant is in default of their payment obligations. The SPMD is also entitled to refuse the issuance of certificates as long as there are justified indications of a breach of the obligation under V Section 2.
4. The payment obligation arises at the time of the conclusion of the contract according to Section III No. 4 of these GTC. It is extinguished exclusively in the event of payment by the participant of these GTC or cancellation of the proficiency test by the SPMD according to Section IV No. 5 of these GTC or in the event of timely deregistration by the participant within the period specified in the registration confirmation.

VI. Evaluation of the interlaboratory test

1. The SPMD evaluates the examination results determined by the participant within the scope of the proficiency test, provided that these are submitted to the SPMD in a timely manner according to the schedule. The participant has no right to evaluation for examination results received late by the SPMD.
2. The entry of the examination results by the participant is made exclusively via the communication channels provided or specified by the SPMD (e.g., online via the RfB online platform). The result evaluation by the SPMD is carried out based on evaluation criteria determined by the SPMD. Where available, the criteria specified in the relevant tables of the guideline of the German Medical Association for quality assurance of laboratory medical examinations (Rili-BÄK) in the currently valid version are applied.
3. The participant receives a certification of the result evaluation for all submitted measured variables/examinations. If the evaluation criteria are successfully met, the participant is additionally issued a certificate by the SPMD listing all measured variables/examination results that match the target specifications. The issuance date corresponds to the submission deadline of the respective proficiency test. In the case of the application of the Rili-BÄK, the validity period of the certificates is regulated by it and applies from the date of issuance. If changes occur due to changed framework conditions (e.g., the basis of the target value has actually changed due to the participant

collective), the SPMD is entitled to issue revised certificates, whereby the originally issued certificates thereby lose their validity.
4. The participant can freely dispose of their evaluations and reports within the scope of the intended use.

VII. Withdrawal, Termination

1. The participant is free to withdraw from participation in a proficiency test until the registration deadline specified in the schedule. Withdrawal is not possible after the registration deadline.
2. If a participant has registered for multiple proficiency tests, there is the option to withdraw from participation in all or only individual proficiency tests. However, this is only possible until the time specified in VII. Section 1 sentence 2.
3. Participants with contract type A can terminate the subscription at any time. From the time of termination, only the proficiency tests for which the registration period has already expired at that time will be delivered. There is also the option to suspend the subscription for an agreed period for one or all registered proficiency tests until the respective registration deadline.
4. Regardless of the contract type, withdrawal and/or termination must be made online via the participant account or by email with reference to the participant registration number. There are no special formal requirements.
5. The SPMD is also entitled to terminate the contractual relationship in accordance with the legal provisions, which also includes termination for good cause.

VIII. Objection/Complaint

1. After receiving the result evaluation, the participant has the opportunity to report any complaints or objections within 14 days to info@rfb.bio or via a contact form specially provided by the SPMD. For this purpose, the customer must clearly describe whether they wish to address a complaint or an objection.
2. All received complaints and objections are handled and reviewed within the scope of the SPMD's complaint management. In the context of a complaint or objection, the SPMD staff will contact the participant. The matter will subsequently be internally reviewed, and the participant will be informed about the investigations carried out or the necessary measures. The final assessment of a complaint/objection must be confirmed by at least one person from the SPMD who is not responsible for the respective proficiency test according to the internal organization, which led to the complaint/objection. The result of the complaint is also confirmed by the management/deputy management of the RfB and the responsible QMB. It is ensured that the complaint or objection does not result in any disadvantage for the complainant. The participant will be informed about the end of the processing of the complaint or objection.
3. In the case of justified complaints or objections, the participants will be contacted by email and informed about any changes and new editions (e.g., 2nd edition report). In any case, the SPMD has the right to choose whether, in the case of a justified complaint, either the invoicing is waived or a replacement proficiency test is conducted. The costs incurred for this, such as

for reagents, time, etc., cannot be reimbursed unless the SPMD is liable for them according to this X.

IX. Liability

1. The SPMD is only liable for damages of any kind – subject to the other prerequisites for liability – in cases of intent and gross negligence, as well as in cases of breach of essential contractual obligations by the SPMD, legal representatives, or vicarious agents, and in cases of lack of guaranteed characteristics. Otherwise, liability for damages of any kind, regardless of the legal basis, is excluded, including liability for claims for damages due to unlawful acts (e.g., so-called "consequential damages") and liability for culpability at the conclusion of the contract.
2. The above liability limitations do not apply to liability for guaranteed characteristics, injury to life, body, or health, or under the Product Liability Act by the SPMD, a legal representative, or vicarious agent.
3. The liability of the SPMD is limited in amount to 25,000 EUR. If the customer is of the opinion that the maximum liability amount does not cover the typically foreseeable damage, they must notify this at the time of placing the order. In this case, the parties will agree on an appropriate maximum liability amount. The maximum liability amount according to sentence 1 does not apply in cases of intentional or grossly negligent conduct by the SPMD or its executive employees. In cases of intentional or grossly negligent conduct by vicarious agents of the SPMD, the maximum liability amount according to sentence 1 does not apply in the event of a breach of cardinal duties. Furthermore, the maximum liability amount according to sentence 1 does not apply in the cases of extended liability listed in paragraph 5. Contrary to this, the maximum liability amount explicitly applies in the case of a breach of cardinal duties in the event of simple/slight negligence, provided that none of the cases of extended liability listed in paragraph 5 are simultaneously present.

X. Confidentiality/Data Protection

1. The SPMD is obligated to mark order-relevant data and store it in a traceable manner. For this purpose, the data and information are recorded and stored for 10 years in a database system, among other things.
2. The SPMD is expressly entitled to use data determined in the course of service provision in an anonymous form for its own purposes, e.g., for statistical surveys or technical evaluations.
3. The customer can object to the use of the data according to No. 3 of this Section IX at any time or revoke a corresponding consent in writing.
4. Notwithstanding the above provisions, the SPMD and the customer undertake to comply with the European Regulation (EU) 2016/679 (General Data Protection Regulation) in its respective applicable version. Further information on data protection can be found at https://www.rfb.bio/cgi?page=Impressum#privacy .
5. The SPMD and the customer mutually undertake to treat all business and personal data, business and trade secrets of the respective other party that become known in the course of the contractual activity as confidential. The transfer of confidential information does not establish any ownership, patent,

or license rights of a contractual partner to the confidential information of the other contractual partner.

6. The data to be treated confidentially include, in particular, trade secrets/information within the meaning of Art. 2 No. 1 of Directive (EU) 2016/943 "on the protection of undisclosed know-how and business information" or § 2 No. 1 of the Trade Secrets Act (GeschGehG).
7. The obligation to maintain confidentiality does not apply to:
    - Information that is demonstrably obtained from generally accessible sources,
    - Information that is already publicly known or 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., information requests from courts and authorities),
    - Inspections of order documents by auditors of the accreditation body,
    - Documents of the SPMD that are subject to disclosure obligations and created for the customer (e.g., certificates),
    - Reporting to an arbitration board in the event of a complaint.
8. The obligation to maintain confidentiality ends 3 years after the completion of the order/end of the contractual cooperation with the customer, unless otherwise agreed with the customer.
9. The SPMD is entitled to further use the assessment results of proficiency tests submitted by the participants in aggregated and anonymized form. The participant is aware that this data will also be published accordingly for the further development of quality assurance on the SPMD's website.

XI. Delivery Stop, blocking

1. The SPMD is entitled to block the account and the delivery of examination materials/certificates in case of an overdrawn account and payment arrears after unsuccessful reminder.
2. The same applies if the participant violates essential obligations under this contract.
3. The SPMD is also entitled to block any access authorization obtained using false or fabricated data.

XII. Contractual Penalty

1. The participant is aware that compliance with the SPMD's specifications in the context of conducting proficiency tests is essential for the SPMD and with regard to regulatory requirements.
2. If the participant culpably violates the above provisions according to Section II. Points 6) to 9), the SPMD can impose an appropriate contractual penalty.
3. In the case of ongoing violations, each calendar month in which the violation occurs in whole or in part is considered an individual case. The objection of continuation is excluded.
4. The amount of the contractual penalty is determined by the SPMD at its reasonable discretion. If it does not correspond to reasonableness, it will be determined by a court judgment.
5. The contractual penalty becomes due upon declaration of its amount to the participant.

6. The contractual penalty has no effect on other claims of the SPMD.

XIII. Copyright

1. Insofar as the services provided by the SPMD are copyrightable, the SPMD reserves the copyright. The participant may only use the evaluation result with all statements and other details and the examination result for the purpose for which it is contractually intended. Any other type of use and any textual modification or abridgment is only permitted to the participant with the consent of the SPMD.
2. This also applies in the case of passing on the evaluation result or the examination results to third parties.

XIV. Changes to the GTC and price adjustments

1. The GTC can be changed to the extent that this is necessary to adapt to developments that were not foreseeable at the time of the conclusion of the contract and that the SPMD did not cause or influence and whose non-consideration would disturb the balance of the contractual relationship to a not insignificant extent and provided that this does not affect essential provisions of the contractual relationship. Essential provisions are those concerning the type and scope of the contractually agreed services and the term, including the provisions on termination.
2. Furthermore, the GTC can be adjusted to the extent necessary to remedy not insignificant difficulties in the execution of the contract due to regulatory gaps that have arisen after the conclusion of the contract. This can be the case, in particular, if the case law on the effectiveness of provisions of these GTC changes, if one or more provisions of these GTC are declared invalid by the case law, 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 in the case of participations already ordered by the participant, the SPMD can adjust the prices to be paid at its reasonable discretion according to the development of the costs that are relevant for the price calculation. A price increase comes into consideration and a price reduction is to be made if, for example, the costs for the production and provision of the products (e.g., procurement costs, transport costs) increase or decrease or if other changes in the technical or legal framework conditions lead to a changed cost situation (e.g., increased regulatory effort, changed legislation for proficiency test providers or in the field of in-vitro diagnostics and medical devices). Increases in one cost type, e.g., infrastructure costs, may only be used for a price increase to the extent that they are not offset by possibly decreasing costs in other areas (e.g., price reductions in the infrastructure area). In the case of cost reductions, the SPMD must reduce the prices to the extent that these cost reductions are not wholly or partially offset by increases in other areas. The SPMD will choose the respective times of a price change in the exercise of its reasonable discretion in such a way that cost reductions are not taken into account according to less favorable standards for the customer than cost increases. Price changes according to this section are only possible at the beginning of a month. The SPMD will inform the customer of the change at least six weeks before the planned effective date in text form. In the event of a price change, the

customer has the right to terminate their respective order in the context of participation in a proficiency test without observing a notice period at the time of the effectiveness of the change in text form. The customer will be separately informed of this by the SPMD in the price change notification. In the event of termination, the price change will not become effective against the customer. Otherwise, § 315 BGB remains unaffected.

4. Independently of the above provisions of the sections, the SPMD is entitled and obligated to adjust the prices accordingly at the time of the respective change in the event of an increase or decrease in the statutory value-added tax, without the customer having a right of termination as a result.

XV. Applicable Law, Jurisdiction, and Salvatory 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 § 1 para. 1 of the 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 is Düsseldorf. The place of performance for all obligations arising from the contract is Bonn, Germany.
3. Should a provision of the contract be or become wholly or partly invalid or unenforceable, this shall not affect the validity of the remaining provisions of this contract. The same applies if a gap in this contract becomes apparent. In place of the invalid or unenforceable provision or to fill the gap, a reasonable provision shall apply that, to the extent legally possible, comes closest to or corresponds to what the contracting parties wanted economically or would have wanted according to the purpose and intent of this contract, had they considered this point. This also applies if the invalidity of a provision is based on a scope of performance or time (deadline or date) provided for in this contract; in such cases, a legally permissible scope of performance or time (deadline or date) that comes closest to the intended economic outcome shall take the place of the agreed provision.