General Terms and Conditions of the

Foundation for Pathobiochemistry and Molecular Diagnostics for Calibration Services and Testing of Standards

(July 2025)

I. Scope

1. The Foundation for Pathobiochemistry and Molecular Diagnostics, based in Bonn, Friesdorfer Str. 153 (hereinafter referred to as **"SPMD"**), fulfils its purpose, among other things, by operating the Reference Institute for Bioanalytics (RfB) as a special-purpose entity. Within this framework, the RfB, with the assistance of affiliated calibration laboratories, also determines target values, known as reference method values, for measurands in laboratory medicine using traceable reference measurement procedures of the highest metrological order. The customer is aware that the calibration laboratories used by SPMD are accredited for the performance of calibrations in accordance with the scope of accreditation specified in the accreditation certificate, which can be viewed at https://rfb.bio/cgi?page=ref_labs.

2. A contract for the services listed below is concluded with SPMD on the basis of its organisational structure. The following terms and conditions apply expressly and exclusively with respect to the performance of calibration services and the testing of standards, which may also include information and advice in this context (hereinafter referred to as **"calibration services"**). Subject to the first sentence of this section 2, the customer's General Terms and Conditions (e.g. Terms and Conditions of Purchase) shall not apply, even if SPMD has not objected to them in individual cases. This shall also apply to future contracts. By accepting SPMD's order confirmation, the customer expressly acknowledges that it waives any legal objections derived from its Terms and Conditions of Purchase.

3. These General Terms and Conditions apply exclusively to traders within the meaning of section 14 of the German Civil Code (BGB). The customer must make a corresponding declaration of its trader status (section 14 BGB) when initiating the order for the first time. Each contract is concluded on the condition that the customer is a trader in the meaning of section 14 of the German Civil Code (BGB).

II. Subject matter and performance of the contract

1. The scope of services applicable in each individual case shall be determined by the respective order confirmation issued by SPMD. A contract for the respective calibration service shall be concluded when SPMD expressly accepts the customer's offer in writing (**"acceptance"**). This acceptance may be submitted at a later date or consist in the performance of the service.

2. SPMD shall not be liable for errors resulting from the documents and information provided by the customer (drawings, samples, material/product specifications and the like).

3. The customer is aware that calibration is primarily only carried out for measurands from the accredited scope. If the requested measurands are not part of the accredited scope, the customer will be informed of this and also that no calibration certificate can be issued and therefore no recognised proof of the metrological traceability of the reference method value. Upon completion of the calibration services, the customer will receive a calibration certificate within the accredited scope or, in case of a non-accredited measurement, a results report from SPMD.

4. The calibration service provided by SPMD will be carried out in accordance with the measurement procedures specified in the accreditation. Unless otherwise agreed, the subject matter of the contract is the calibration of sample material (hereinafter referred to as **“calibration item”**) with regard to clinical measurands and the issuance of corresponding calibration certificates/results reports by SPMD. Conformity assessment of the customer's calibration item by the laboratory is expressly excluded from the scope of the contract.

5. After the calibration work has been carried out by SPMD in accordance with the agreed scope, the customer will be notified of the result (hereinafter referred to as the result) by means of a calibration certificate/results report, thereby fulfilling SPMD's contractual obligation.

6. The calibration services/tests of standards accepted by SPMD shall be carried out in accordance with the recognised rules of technology, taking into account the state of the art, unless otherwise agreed in writing.

7. If calibration services are performed outside the scope of accreditation, this shall and must be indicated.

8. Foreign customers shall provide their international VAT identification number when concluding the contract. Customers from other European countries may be exempted from German VAT upon notification of their EU VAT ID.

9. Information and advice regarding calibration services and their result shall be provided exclusively on the basis of SPMD's previous experience. The values and procedural steps specified herein are to be regarded as average values or standard procedural steps. All information about result of calibration services, in particular the accuracy, measurement and performance data contained in the offers and/or other printed documents of SPMD, as well as other technical data, are to be regarded as approximate average values, unless SPMD has expressly designated them as “binding”.

III. Calibration item

1. The customer must declare the calibration item properly. The customer must send the calibration item to the location specified by SPMD. In doing so, the customer shall ensure that no personal data relating to the calibration item is sent to SPMD. SPMD and the customer shall jointly determine a shipping date and the number and volume of the portions of the calibration item required for the provision of services. The calibration item shall be shipped to the location specified by SPMD at the expense and responsibility of the customer. The customer shall ensure that all documents required for transport are available and, if necessary, can be requested by SPMD from the relevant authorities. Shipping shall normally be carried out in accordance with UN3373 Category B – Transport of biological substances. Biological substances of category A must be rejected by SPMD. The customer shall also ensure that the calibration item is packed in a liquid-tight container, surrounded by an additional outer shell and properly cooled. In all other respects, the transport conditions of SPMD apply, which can be found at https://www.rfb.bio/pdf/Probentransport_handling%20of%20samples.pdf.
2. The risk of accidental loss or deterioration of the calibration item shall only pass to SPMD under the aforementioned transport conditions and in any case only upon arrival of the calibration item at the location specified by SPMD in accordance with the following conditions.
3. Before the calibration item is received by the location specified by SPMD, the customer shall instruct SPMD as to what type of storage or, if necessary, other special handling of the calibration item it deems necessary. If it fails to provide such instructions, SPMD shall determine the type of storage and handling at its own discretion.
4. If, upon delivery to SPMD, the calibration item is in a condition that casts doubt on its suitability or does not correspond to the description contained in the accompanying delivery note, SPMD shall be entitled to withdraw from the contract after consultation with the customer without the customer being entitled to any claims against SPMD.
5. If doubts arise during the calibration work as to the suitability of the calibration item, a decision on whether to continue the calibration work shall be made jointly with the customer. In the event of termination of the calibration work, the work performed up to that point shall be remunerated. A lack of suitability of the calibration item shall be assumed in particular in the event of instability and/or inhomogeneity of the sample.
6. The customer is expressly advised that the documented result only reflects the actual condition of the calibration item at the time of calibration by SPMD under the environmental conditions prevailing at that time.
7. However, SPMD reserves the right to request further filling of the calibration item from the customer in order to verify the calibration result.

8. The customer is aware that the calibration item is usually destroyed during testing and/or assessment. If sample material is still available from the calibration item (hereinafter referred to as **"residual material"**) after testing/assessment, the customer agrees that SPMD may use this for validation and research purposes. This may involve measurements to check the measurement accuracy (control measurements) or to verify, optimise or assess individual steps of the reference procedure. The residual material shall be retained and used for a maximum period until the expiry of its stability. Only residual material shall be reused.

9. The customer shall deliver the calibration item to SPMD free of charge and free of customs duties. This also applies to clause 7. The risk and costs of freight and transport of documents or the calibration item or further test specimens to and from SPMD shall be borne by the customer.

10. In the case of delivery from abroad, the customer is responsible for all customs formalities. SPMD will assist the customer in this regard at its own discretion as a courtesy, whereby any liability on the part of SPMD in this connection is excluded. With regard to any costs incurred in this connection, reference is made to clause 9.

11. During the storage period of the calibration item and/or other test specimens, SPMD shall only be responsible for the care that it would normally apply in similar cases (§ 690 BGB).

12. The customer is aware that they are responsible for any retention samples. SPMD will not retain any retention samples.

13. The testing of the calibration item at SPMD or at calibration laboratories designated for this purpose shall be completed upon dispatch of the result, unless otherwise agreed between the customer and SPMD.

14. SPMD shall not be liable for the information provided by the customer regarding the calibration item. This information shall only be checked for plausibility. For the purpose of verifying the calibration items/test specimens delivered, e.g. in the context of expert reports, retention samples may be retained. However, the obligation to retain such samples lies with the customer.

IV. Applicability of DIN EN ISO

If, in the course of the execution of this contractual relationship, a dispute arises between the contracting parties regarding the content of IT/technical terms, quality requirements, format requirements or similar, the relevant standards applicable at the time of conclusion of the contract (DIN EN ISO 15195, DIN EN ISO/IEC 17025, DIN EN ISO 17511) applicable at the time of conclusion of the contract shall apply. In all other respects, the technical rules and regulations in accordance with the state of the art shall always apply.

V. Recalling and revision of result based on the calibration services performed

1. SPMD shall prepare its written documentation (e.g. result) carefully and conscientiously. If there are justified indications that written documentation is incorrect, SPMD is obliged to recall the relevant documentation, regardless of the cause of the incorrectness. In this case, the customer is obliged to refrain from further use of the written documentation. SPMD shall inform the customer of the necessary destruction of the documentation.
2. From the time of recall or provision of a revised version of the results, SPMD shall assume no further liability for the usability and use of the original/incorrect results. It shall be entitled to withdraw the results.
3. If there are reasonable grounds for believing that a supplementary test is necessary, SPMD shall be entitled to carry out such a supplementary test. If the need for a recall is caused by SPMD, the results shall be corrected or, if possible, the test material shall be recalibrated. If material has to be sent again by the customer, the formalities and costs shall be agreed between the customer and SPMD.

VI. Service provision by third parties

1. SPMD shall generally provide the service through laboratories that are accredited for SPMD. However, SPMD shall also be entitled to subcontract individual parts of the range of services to suitable subcontractors.
2. The customer shall give its consent to the commissioning of third parties by SPMD when placing the order, which SPMD shall accept. The customer's consent to the provision of services by third parties in the aforementioned sense shall be deemed to have been given upon conclusion of the contract, provided that this is apparent from the documents leading to the conclusion of the contract and the customer has been granted a reasonable period of time to make an express declaration and has been informed of the legal consequences of failure to consent. In this case too, SPMD shall remain the sole contractual partner of the customer.
3. SPMD shall be liable to the customer in accordance with these terms and conditions for any fault on the part of the subcontractor.

VII. Performance period, delays

1. Information regarding delivery and performance dates is non-binding unless SPMD has designated it as binding in writing. SPMD may provide partial services insofar as the delivered parts are useful to the customer. Unless otherwise agreed, the performance period shall commence upon delivery of the sample to SPMD at the earliest.
2. The agreement of a fixed performance date is subject to SPMD receiving the necessary deliveries and services from its respective suppliers in good time and in accordance with the contract.
3. Delivery and performance deadlines shall be extended by the period during which the customer is in default of payment under the contract and by the period during which SPMD is prevented from delivering or performing due to circumstances for which it is not responsible, and by a reasonable start-up period after the end of the hindrance. These circumstances also include force majeure and industrial action. Deadlines shall also be deemed extended by the period in which the customer fails to perform a contractual obligation, e.g. fails to provide information, fails to grant access, fails to deliver an order or fails to make employees available.
4. The occurrence of default shall be determined in accordance with the statutory provisions. In any case, however, a reminder from the customer is required.
5. In the event of a delay in performance, the customer shall only have a right of withdrawal within the scope of the statutory provisions if the delay is for which SPMD is responsible.

VIII. Complaints/liability/limitation of liability

1. Complaints against SPMD for non-contractual performance of the contract must be made within 12 weeks. The period begins with the dispatch of the result or other written notifications from SPMD regarding the services performed. In cases of doubt, the date of the dispatch note of the result, other notification or cost statement shall be binding. After expiry of this period, claims by the customer due to a complaint shall be excluded. In all other respects, the provisions under section V shall apply.
2. SPMD shall be liable for all culpably caused damage, including that caused by its representatives or vicarious agents in cases of intent and gross negligence.

3. In case of

   - injury to life, limb or health,
   - damage covered by the Product Liability Act,
   - damage resulting from the breach of a cardinal obligation (cardinal obligations are obligations whose fulfilment is essential for the proper execution of the contract and on whose fulfilment the customer may regularly rely),
   - breach of quality agreements and fraudulent concealment of defects

   SPMD shall also be liable for ordinary negligence and thus for any fault on the part of its representatives or vicarious agents.

4. In the event of a breach of cardinal obligations, liability shall be limited to the amount of the foreseeable damage typical for the contract, unless another of the cases of extended liability listed in paragraph 3 applies at the same time.

5. SPMD's liability shall be limited to 25,000 euros. If the customer believes that the maximum liability amount does not cover the foreseeable damage typical for this type of contract, it must notify SPMD of this when placing the order. In this case, the parties shall agree on an appropriate upper limit of liability. The maximum liability amount pursuant to sentence 1 shall not apply to grossly negligent or intentional conduct on the part of SPMD or its executive employees. In the event of grossly negligent or intentional conduct 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. The maximum liability amount pursuant to sentence 1 shall also not apply in the cases of extended liability listed in paragraph 3. Notwithstanding this, the maximum liability amount shall expressly apply in the event of a breach of cardinal obligations in the case of simple/slight negligence, unless another of the cases of extended liability listed in paragraph 3 also applies.

6. The above provisions apply to all claims for damages (in particular for damages in addition to performance and damages in lieu of performance), regardless of the legal basis, in particular due to defects, breach of obligations arising from the contractual relationship or from tort (e.g. so-called “further damage”). They also apply to claims for reimbursement of futile expenses. Liability for delay remains unaffected.

7. The above provisions do not imply any change in the burden of proof to the detriment of the customer.

8. The customer is obliged to indemnify SPMD against any claims for compensation by third parties if it continues to use RESULTS even though these have been recalled by SPMD in accordance with section V.

IX. Email communication and obligation to update

When registeringti the participant undertakes to provide a validti active email address at wich they can be reached for the delivery of contract-related communicationsti in particular invoices and reminders. The participant shall ensure that electronic receipt via this address is technically possible

and that the address is regulary checked for new messages. Changes to the email address must be communicated to SPMD immediately by email.

X. Access to electronic communications

Communications from SPMD to the email address provided by the participant shall be deemed to have been received as soon as they have been vierifiably sent to this address and can be accessed under normal circumstances. This shall not apply if the participant can credibly demonstrate that they did not receive the communication despite having reasonable technical equipment for receiving it.

XI. Delays in email delecery

If the receipt of an invoiceti reminder or other contractual notification by email is not possible or is delayed due to technical or organistional failures on the part of the customerti the customer shall bear the disadvantages caused by thisti including any missed deadlines and default costs. In this contextti SPMD may charge a flat-rate processing fee of EUR 5.00 per incident if an additional internal effort is required due to a missing or outdated email address (e.g. manual redeliveryti queriesti system corrections) and the customer is responsible for this.

XII. Collection and use of data

1. Within the scope of its activities, SPMD is obliged to label data relevant to the order and store it in a traceable manner. For this purpose, the data and information are recorded in a database system and stored for 10 years.
2. SPMD shall be entitled to use data determined in the course of providing its services (e.g. test specimen descriptions) and results (e.g. test and classification values) in anonymised form 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 by SPMD in accordance with 2 above at any time or revoke their consent in writing.
4. Notwithstanding the above provisions, SPMD and the customer undertake to comply with European Regulation (EU) 2016/679 (General Data Protection Regulation) in its currently valid version. Further information on data protection can be found at https://www.rfb.bio/cgi?page=Impressum#privacy.

XIII. Confidentiality/Handling of trade secrets

1. 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 contractual partner to the confidential information of the other contractual partner.

2. Data to be treated as confidential includes, in particular, trade secrets/information within the meaning of Art. 2 (1) of Directive (EU) 2016/943 “on the protection of confidential know-how and confidential business information” or § 2 (1) of the German Trade Secrets Act (GeschGehG).
3. The obligation of confidentiality does not apply to:
    - information that demonstrably originates from publicly accessible sources,
    - information that is already publicly available or generally known or corresponds to the current state of the art,
    - information which 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 auditors of the accreditation body,
    - SPMD documents created for the customer which are subject to publication (e.g. certificates),
    - reporting to an arbitration board in the event of a complaint.
4. The obligation to maintain confidentiality shall end three years after completion of the order/end of the contractual cooperation with the customer, unless otherwise agreed with the customer.

XIV. Applicable law, place of jurisdiction

1. The contract concluded between the customer and SPMD is subject to the law of the Federal Republic of Germany, subject to mandatory provisions of international private law, as agreed by the parties involved.
2. To the extent permissible, the courts in Cologne shall have exclusive jurisdiction for all disputes arising from or in connection with the contractual relationship in question. The place of performance for all obligations arising from the contract is Bonn, Germany.