



General Terms and Conditions

of Genome Identification Diagnostics GmbH, Department Immune Analytics

1. General Validity and Definitions

- 1.1 The following General Terms and Conditions apply to all offers created by and agreements between Genome Identification Diagnostics GmbH (“GenID GmbH”), Ebinger Str. 4, DE-72479 Strassberg, Germany, and contractual partners regarding services of its department “Immune Analytics” as well as the development and validation of bioanalytical assays used for these services.
- 1.2 Immune Analytics belongs as Contract Research Organization to the GenID GmbH, to provide analytical services to interested contractual partners in the scientific, preclinical, clinical and pharmacological research field (“Sponsor”).
- 1.3 The General Terms and Conditions shall apply in its most recent version at the date set down on GenID GmbH’s offer or the executive date of the agreement and shall also govern all subsequent transactions between the parties without any need of express reference thereto.
- 1.4 Any dissenting provisions of the Sponsor shall not apply except GenID GmbH has expressly confirmed the same in writing, even if GenID GmbH fulfills its contractual obligation without reservation in the awareness of the conflicting provisions of the Sponsor.
- 1.5 In the event GenID GmbH’s services comprise the manufacturing of IVD kits, these General Terms and Conditions shall also apply. The details of manufacturing and admission shall be subject to a separate agreement.
- 1.6 As far as the General Terms and Conditions refer to “writing” or “written” form, the following shall apply:

Electronic mails fulfill the written form requirement unless otherwise stated for a particular declaration within these General Terms and Conditions, the offer or the contract. Oral statements require the written confirmation to be effective. This shall also apply to a waiver of the written form requirement.

2. Services and Quality / Support

- 2.1 “Services” shall mean the analytical services to be provided by GenID GmbH to Sponsor, as defined within the offer, the contract and/ or the study plan. In the event the definitions of Services within these documents diverge, the most recent version shall prevail.
- 2.2 GenID GmbH’s obligations are defined by the Services and the quality policy as laid down in the Immune Analytics “Quality Management Handbook” with references to



further standards and documents. Obligations of GenID GmbH to comply with GLP or GCLP standards have to be set down in the offer, the study plan and/or otherwise by contract.

- 2.3 GenID GmbH reserves the right to provide the Services or parts thereof by subcontractors in coordination with the Sponsor unless otherwise stated within the offer or the contract.
- 2.4 The Sponsor will provide GenID with any necessary information and use its best efforts to support GenID in the provision of Services.

3. Offer and Contract Conclusion

- 3.1 Upon request, GenID GmbH provides to Sponsor an offer containing provisions including but not limited to methodology, prices, timelines and deliverables as far as already determinable.
- 3.2 GenID GmbH's offers are always subject to change and non-binding, in particular with reference to timelines and prices, unless they are limited in time.
- 3.3 Offers, the modification and acceptance of an offer as well as the creation and modification of the study plan and any other agreements have to be made in writing. As regards to declarations and agreements under this section 3.3, electronic mails do not fulfill the written form requirements.

4. Samples and materials

- 4.1 Unless otherwise agreed between the parties in writing, it is the Sponsor's sole responsibility to provide GenID GmbH with the samples, materials and other information to the extent necessary for the provision of the Services. In particular, samples and materials have to be delivered in time and under proper conditions as required by the nature of the samples and materials and/ or as stated within the offer or the contract.
- 4.2 Unless otherwise agreed, the requirements for the quality and delivery of samples and materials are following general scientific standards.
- 4.3 The burden of proof regarding the completeness and the proper condition and delivery of materials, samples and further information lies with the Sponsor.
- 4.4 Samples and materials that are not used up by the provision of Services will be stored at GenID GmbH's premises under adequate conditions until the end of the project except if otherwise stated within the offer or agreed between the parties subsequently. After termination of the project, the samples and materials will be destroyed or returned to Sponsor at his cost and discretion. The selection of the method of destruction or the transport route and the means of transport shall, in the absence of any written



- agreement stating otherwise, be subject to GenID GmbH's reasonable and expert discretion and be without liability for the cheapest and fastest version.
- 4.5 In the event the Sponsor requests for a further storage of samples and/ or materials after termination of a project, this may be subject to further costs and needs to be agreed between the parties in writing. GenID GmbH may reject any further storage due to capacity reasons.

5. Third party rights / Indemnification

- 5.1 In the event that any of the materials or information provided by Sponsor and/ or the use and analysis thereof is subject to third party rights, Sponsor indemnifies and holds GenID GmbH harmless against any claim by the third party to the extent as permitted by law.
- 5.2 This indemnification includes but is not limited to:
- the reimbursement of any payment of GenID GmbH to the third party due to a claim of their above-mentioned rights;
 - the reimbursement of reasonable attorneys-at law's and patent attorney's fees for the defense against claimed third party rights and related consultancy;
 - the reimbursement of further damages of GenID GmbH that are caused or will be caused by the allegation of an infringement of third party rights;
 - the indemnification against further claims caused by the allegation of infringement.
- 5.3 GenID GmbH reserves all rights to claim damages resulting from the third party rights encumbrance, including any loss of profits.

6. Force Majeure / Delays caused by Sponsor

- 6.1 If a case of force majeure occurs, GenID GmbH shall not be responsible for the delay or inability caused by such incident. Force majeure means any incident that is beyond GenID GmbH's control and where the impacts on the performance of the Services cannot be avoided by reasonable efforts of GenID GmbH, namely acts of war (whether declared or undeclared), a state of quasi-war, insurrection, revolution, rebellion, military or civil coup, revolt, uproar, riot, blockade, embargo, government act, sabotage, strike, goslow, lock-out, epidemic disease, fire, flood, storm, hurricane, earthquakes, landslide, lightning, general shortage of fuel, heavy transport accidents, any destruction or new production of material parts of the plant due to reasons outside GenID GmbH's control to the extent this leads to an extension of the timelines or the impossibility of performance.



- 6.2 In this event, GenID GmbH is entitled to re-schedule the timelines and delivery dates or to withdraw from its contractual obligations at its sole discretion. If a later performance of the services is unusable for the purpose as determined within the offer or the contract or the samples cannot be provided at a later date, the parties will mutually agree on a balance of interest.
- 6.3 The same applies in any case of delay in the performance of Services caused by the late or inadequate fulfilment of the Sponsor's obligations.
- 6.4 GenID GmbH reserves all rights to claim damages resulting from Sponsor's delay in fulfilling its obligations, including but not limited to the extended provision of laboratory and storage capacities.

7. Deliverables/ Reports

- 7.1 Unless otherwise agreed between the parties, the place of performance for deliveries, if any, shall be the place of GenID GmbH's registered office in Strassberg, Germany.
- 7.2 As regards to reports, data and results that shall be transmitted electronically, the parties will mutually agree on the conditions of transmission (e.g. recipient email addresses, encryption, mode of transmission etc.).
- 7.2 After completion of the Services, GenID GmbH will inform the Sponsor about the availability of deliverables. The selection of the transport route and the means of transport shall, in the absence of any written agreement stating otherwise, be subject to GenID GmbH's reasonable and expert discretion and be without liability for the cheapest and fastest version.
- 7.3 Unless otherwise stated within the offer, GenID GmbH provides to Sponsor a final report including all results and data generated by providing the Services after finalization of analyses.
- 7.4 GenID GmbH shall have the right to a reasonable partial delivery to the extent compatible with the study plan.
- 7.5 Any delivery to third parties or to any destination that does not correspond to the address of Sponsors principal place of business can only occur if expressly instructed in writing and under the full assumption of risk and responsibility of any loss or damage by Sponsor. Sponsor shall bear any additional shipping costs

8. Intellectual Property / Results / Title

- 8.1 Each party will remain the owner of any intellectual property rights (including but not limited to know-how, inventions, patents, utility models, copyrights, reports and data) that it has held or developed prior to the contractual relation.



- 8.2 Unless otherwise agreed in writing, all results, data, documents and reports resulting from the Services shall become the sole property of the Sponsor upon full payment.
- 8.3 Notwithstanding the regulation in 8.2, inventions and improvements of assays, methods, kits and reader systems developed while providing the Services shall be the sole property of GenID GmbH or the respective sister company. Sponsor shall have no right to use such inventions or improvements unless otherwise explicitly permitted.
- 8.4 Anonymized data and results can be used by GenID GmbH for internal scientific purposes and the development and improvement of assays, methods and reader systems as well as for regulatory purposes.
- 8.5 GenID GmbH has a right to use any know-how gained while providing the Services without limitation, as far as this know-how can be used independent of any specific Sponsor samples and information and personal data.
- 8.6 IVD kits and testing devices manufactured by GenID GmbH are the property of and will remain with GenID GmbH.

9. Prices and terms of payment

- 9.1 Prices are exclusive of the respective statutory VAT and exclusive of costs for packaging and return of samples, except as otherwise expressly agreed upon.
- 9.2 Payments shall be made in Euro or, where the offer states otherwise, in that currency.
- 9.3 Payments are due and payable net within 30 days from the date of the invoice except as otherwise specified in GenID GmbHs offer.

10. Set off / Assignment

- 10.1 The Sponsor shall have no right to set off, retention or reduction unless the underlying counterclaims have been conclusively determined by a court or expressly acknowledged by GenID GmbH.
- 10.2 The Sponsor's contractual rights and obligations shall not be assigned or transferred except with the written consent of GenID GmbH.

11. Warranty and notices of defects

- 11.1 Precondition for any warranty claim of the Sponsor is the adequate delivery and proper quality of samples and materials as stated above as well as the Sponsor's full compliance with all following requirements regarding inspection and reporting.
- 11.2 The Sponsor must examine the deliverables promptly following delivery by GenID GmbH insofar as this is practicable in the orderly course of business and, if a defect becomes apparent, inform GenID GmbH without undue delay.



- 11.3 Unless otherwise agreed between the parties, Sponsor is obliged to examine reports and accept them by signature within one (1) month following delivery of the respective report, or – if any – inform GenID of any defect of the report or the Services as they are apparent from the report. By its signature, Sponsor approves accuracy of the Services provided by GenID GmbH to the extent as they are apparent from the report.
- 11.4 If the Sponsor fails to advise GenID GmbH, the deliverables and reports are deemed approved, unless there is a defect, which was not apparent during the examination.
- 11.5 Where such a defect becomes apparent at a later time, notice must be given promptly following the discovery; otherwise the deliverables and reports are deemed approved, also with regard to this defect.
- 11.6 The Sponsor's rights are preserved by timely sending of notice.
- 11.7 Where GenID GmbH has maliciously concealed the defect, GenID GmbH may not assert these provisions.

12. Liability

- 12.1 GenID GmbH will provide the Services in accordance with the state of science and technology and its quality management system as laid down in the "Quality Management Handbook Immune Analytics" and the therein referenced standards and documents.
- 12.2 GenID GmbH shall not be liable for the reports, results or deliverables being fit for a particular purpose as far as not specified within the offer or the agreement.
- 12.3 In the event of a breach of material contractual obligations ("Kardinalpflichten"), GenID GmbH shall be liable for damages caused by intent and any negligence. Material contractual obligations are duties, which must be complied with in order to ensure the proper performance of the contractual relation and the compliance with which can be reasonably relied upon by the Sponsor.
- 12.4 In all other cases, GenID GmbH shall only be liable to Sponsor for damages caused by intent or gross negligence.
- 12.5 Any liability for damages caused by GenID GmbH's negligence shall be limited to the contract-typical, foreseeable damage without any liability for Sponsor's loss of profits.
- 12.6 The above-mentioned limitations of liability shall neither apply in the event of injury to life, body or health nor to claims under the German Product Liability Act (Produkthaftungsgesetz).
- 12.7 In the event the Services are not duly performed, the Sponsor has sufficiently claimed the default and GenID GmbH is responsible for it, GenID will re-perform the Services or parts thereof to the extent this does not require an unreasonable amount of effort and the necessary samples and materials are still available.



13. Confidentiality

- 13.1 GenID GmbH and Sponsor shall treat the confidential information obtained from the other party in connection with the Services (“Confidential Information”) as confidential and neither disclose it to any third party nor use it for any purpose other than the performance of the cooperation. Confidential Information means any information that is clearly marked as confidential or ought to be considered confidential from its nature.
- 13.2 The confidentiality obligations shall not apply if and to the extent the Confidential Information
- a) is or becomes generally known through no act or omission of the receiving party;
 - b) has been or will be received by a third party without any breach of confidentiality obligations;
 - c) was or is developed independently of the cooperation by the receiving party;
 - d) is excluded from confidentiality obligations by written statement of the disclosing party;
 - e) has to be disclosed by law or under court or governmental order; the parties will inform each other of any such disclosure without undue delay.
- 13.3 GenID GmbH and Sponsor shall ensure that employees and third parties involved in the Services are bound by confidentiality obligations at least as strict as the ones under these General Terms and Conditions and inform them about the confidential nature of the respective information.
- 13.4 Press releases and publications containing the cooperation of the parties require the prior written consent of the other party.

14. Data Security

- 14.1 The responsibility regarding the patients consent to the transfer of its data to GenID GmbH, the processing of the data by GenID GmbH and the transfer of the resulting diagnosis data back to the Sponsor as well as the compliance with the further provisions of the Regulation (EU) 2016/679 (General Data Protection Regulation) concerning human samples and materials lies with the Sponsor.
- 14.2 Human samples and materials have to be provided by the Sponsor without reference or recognizability of the respective patient (“blinded”). In the event GenID GmbH notices that a sample is delivered in an unblinded status or an unblinding appears through the provision of services, GenID GmbH will notify the Sponsor’s data security contact person as defined within the study plan without undue delay.
- 14.3 GenID GmbH handles human samples and materials in accordance with the legal requirements and its Standard Operation Procedures.



15. Sponsor Data

GenID GmbH stores data of the Sponsor in accordance with the Regulation (EU) 2016/679 (General Data Protection Regulation).

16. Applicable law and jurisdiction

16.1 For GenID GmbH's benefit, the District Court of Stuttgart, Germany shall have jurisdiction over all disputes arising from the contractual relationships. However, GenID GmbH may also select a different place of jurisdiction.

16.2 The laws of the Federal Republic of Germany shall apply under exclusion of International purchase law. This exclusion shall, in particular, refer to the UN Convention on the International Sales of Goods (CISG).