Annex No. 2

Rīga Stradiņš University

Intellectual property auction

*“Innovative genetic test*

*for determining the causes of infertility “Genterf””*

 Regulations

(Auction No. 2021/02)

LICENCE AGREEMENT

(draft)

Riga, THE DATE OF SIGNATURE OF THE DOCUMENT IS THE DATE OF THE LAST ADDED SECURE ELECTRONIC SIGNATURE AND ITS TIME STAMP

**Rīga Stradiņš University**, Reg. No. 90000013771, represented by its Rector Aigars Pētersons, acting on the basis of the RSU Constitution, hereinafter referred to as the Licensor, on the one hand,

and

\_\_\_ “\_\_\_\_\_\_\_\_\_\_”, registration number \_\_\_\_\_\_\_\_\_\_, legal address: \_\_\_\_\_\_\_\_\_\_, represented by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ acting on the basis of \_\_\_\_\_\_\_\_\_\_, hereinafter referred to as the Licensee, on the other hand, hereinafter jointly referred to as the Parties,

in view of:

* Section 39.5 of the *Law on Scientific Activity*,
* Paragraphs 31.4, 31.4.1 of Regulations of the Cabinet of Ministers No.692 of 25 October 2016 *“Implementing Regulations of Activity 1.2.1.2 “Support for Improvement of Technology Transfer System” of Specific Objective 1.2.1 “To increase Investments of Private Sector in R&D" of the Operational Programme “Growth and Employment””*,
* Section 29(2) of the Trademark Law, and
* the results of the written Auction for the intellectual property with descending-price step *“Innovative genetic test for determining the causes of infertility “Genterf””* (Auction No. 2021/02),

enter into this agreement (hereinafter referred to as the Agreement):

1. EXPLANATIONS OF THE TERMS USED IN THE AGREEMENT

* 1. Licensor – Rīga Stradiņš University – owner of the Know-how and the Trademark;
	2. Licensee – the subject, which the right to use the Know-how and at the same time the right to use the Trademark has been granted under this Agreement;
	3. Know-How – the intellectual property owned by the Licensee *“Innovative genetic test for determining the causes of infertility “Genterf””*. The know-how, inter alia, includes the following characterising and complementing information elements:

1.3.1. Method conducting principle, hardware to be used, data interpretation manual with IT solutions developed with appropriate criteria;

1.3.2. Detailed description of the variations included;

1.3.3. Analytical sensitivity and specificity verification documentation;

1.3.4. Stability study data;

1.3.5. Results of the Genterf preclinical trial, including more than 400 individuals with different reproduction-related phenotypes.

* 1. Trademark – the trademark “Genterf”, registration number M 75 588, date of registration 20.06.2020 registered as property of the Licensor;
	2. Area of operation (licence) – European Union;
	3. Genetic test – the test created as part of the Know-how, which the Licensee is entitled to use in accordance with the Agreement, including within the framework defined in chapter 3 of the Agreement;
	4. License fee – the fee paid by the Licensee to the Licensor for the acquisition and use of a licence in accordance with Chapter 5 of the Agreement.

2. SUBJECT-MATTER OF THE AGREEMENT

* 1. For the fee defined in the Agreement and for the period defined in the Agreement the Licensor provides the Licensee with an exclusive license for the production, selling and other use of the Know-how Genetic Tests in accordance with Chapter 3 of the Agreement in the territory of operation of the Agreement, the European Union.
	2. Along with the license specified in Clause 2.1 of the Agreement under the Agreement the Licensee obtains the right in the form of an exclusive licence (Section 29(2) of the Trademark Law) to use the “Genterf” trademark, registration number M 75 588, registration date 20.06.2020, registered as property of the Licensor.
	3. Under the Agreement issuing of a licence is not considered alienation of the ownership of the Know-How or Trademark in favour of the Licensee.

3. SPECIFIC LIABILITIES OF USE OF THE KNOW-HOW

* 1. The Licensee, in accordance with its actual possibilities performs support activities to promote effective economic use of the Know-How and the Genetic Test, and specifically:

3.1.1. The Licensor, by involving also authors of the Know-How, within a period of 6 (six) months of the entry of the Agreement into force shall provide the Licensee with advisory support in the use of the Know-How, incl. production of the Genetic Test. The scope of consultations shall be determined in the amount the Licensee needs, but no more than 16 (sixteen) hours per month, unless the Parties agree otherwise;

3.1.2. The Licensor shall take the actions specified in regulatory enactments to conduct the clinical trial of the Genetic Test. The Licensor shall provide the Licensee with complete information and documentation relating to the clinical trial. The clinical performance study of the “Genterf” genetic test will be concluded on 31 May 2022 and the results obtained will be transferred to the Licensee without additional charge. The study of the GENTERF has received the authorisation of the Central Ethical Committee No. 01-29.1.2/3269 and the authorisation of the State Agency of Medicines, the identification number of the study in the European Database on Medical Devices EUDAMED is CIV-LV-20-12-035444;

* 1. The Licensee is entitled to use the Know-How for the production, storage, use, import, export, offer for sale, sale and other release for economic circulation of the Know-How Genetic Test in the European Union. This includes also the right to implement procedural activities and other communication with the State Agency of Medicines and other supervisory, controlling or cooperation authorities to fulfil the requirements set in regulatory enactment.
	2. Within the scope of the activities specified in Clause 3.2 of the Agreement, the Licensee shall independently assume responsibility for the implementation of the activities in accordance with regulatory enactments and assumes responsibility towards third parties. The Licensee shall also independently assume responsibility for compliance with the requirements included in regulatory enactments, the Agreement and the documentation describing the Know-How with regard to production storage, transportation of the Genetic Test and other aspects to ensure complete validity of content, technical, functional and other properties and parameters.
	3. The Licensee is not entitled without prior written coordination with the Licensor to transfer the Know-How or its individual elements to third persons. The Licensee is not entitled without prior written coordination with the Licensor to issue sub-licenses.
	4. The Licensee is entitled to handle the Know-How, to indicate the Licensor as the author and owner of the Know-How, and as the owner of the Trademark. In this context, the Licensor is entitled to request to configure and coordinate the content and type of the specific information to be published.
	5. If the Parties agree separately, the Licensor shall reserve the right to further use of the Know-How for research.

4. CONFIDENTIAL INFORMATION AND TRADE SECRET

4.1. All the information (written or oral, or in other format) received and transferred under the Agreement shall be considered a trade secret and confidential information (hereinafter jointly referred to as Confidential Information), including any information about the Know-How and the Trademark, including, but not limited to the information, which can be used to create a similar know-how or genetic tests.

4.2. Non-disclosable information and materials under the Agreement shall not be the information and materials, which meets at least one of the following indications:

a) the information or materials are generally known;

b) the information or materials, the obligation of disclosure of which arises from regulatory enactments and which are disclosed in accordance with the procedure provided for by the regulatory enactments;

c) the information characterising, explaining or justifying positive properties, functionality, uniqueness of the Know-How and the Genetic Test (for example, to users, patients, customers, etc. of the Genetic Test), at the same time ensuring that no information, which may directly lead to the creation of similar products by third parties is disclosed.

* 1. When deciding on handling of the Confidential Information and when handling the Confidential Information, the Parties are bound by the norms of the Trade Secret Protection Law and other regulatory enactments, including the principle defined in the Civil Law that rights should be exercised and duties should be performed in good faith.
	2. The Parties undertake not to disclose the Confidential Information specified in Sub-Clause 4.1 of the Agreement to third parties, assuming responsibility under this Agreement for the losses, incl. lost profit and costs, which the other Party might incur in relation to the commitment defined in this Clause. This does not apply to the disclosure of necessary information to official state institutions to implement the functions and tasks defined for them in regulatory enactments.
	3. The Licensee shall ensure the conclusion of full and relevant confidentiality agreements with its employees or any natural or legal persons, who work with the Know-How and the Genetic Tests. Action of subjects is permitted and limited only in the context of fulfilment of liabilities under the Agreement.
	4. The Parties undertake to store and protect the Confidential Information and observe reasonable preconditions for storage of information. In case of doubts relating to the Confidential Information, the Parties shall refrain from actions, unless the action is coordination with the other Party. Having received objections of the other Party regarding handling of the Confidential Information, the Party shall stop the actions until the circumstances are jointly evaluated and a mutually agreed solution is reached. In this case, none of the Parties shall put unjustified obstacles to the implementation of rights of the other Party when handling the Confidential Information in a legal and correct way.
	5. When terminating the Agreement for any reason, the Licensee shall immediately, but no later than within 7 (seven) days, with a mutually prepared statement return to the Licensor all the Confidential Information received from it in any form and shall destroy or delete all duplicates or copies of information stored in paper form, or electronic form, or other from. When signing the statement, the Licensee shall certify and assume responsibility that it acted in accordance with this Clause and further availability of the information to the Licensee or third parties in relation to the Know-How is excluded. Exceptions are permissible to the extent the Licensee is able to justify that they are based on imperative requirements of regulatory enactments or legal requirements of official authorities.
	6. If at least one of the Parties deems this necessary, the Parties shall sign acceptance and transfer certificates on the fact, scope, content and other aspects of the Confidential Information transferred to the other Party.
	7. The Parties shall also observe the rules of processing of personal data:

4.9.1. If any documents or information are obtained within the scope of the Agreement, which contain or may contain personal data of natural persons (hereinafter referred to as the Data), the Parties are entitled to process the data obtained from the other Party only for the purposes of ensuring the fulfilment of liabilities under the Agreement, in line with the requirements set in applicable regulatory enactments for processing and protection of personal data. When processing the Data, each Party shall be responsible for ensuring the processing of the Data in accordance with provisions of the Agreement and regulatory enactments. Under the Agreement each Party shall be liable to implement relevant technical and organisational measures to ensure and be able to demonstrate that the Data are processed in accordance with the regulatory enactments regulating the processing of Data;

4.9.2. When processing the Data, the Parties shall ensure that only authorised persons can access the technical resources used for the processing and protection of personal data (and also personal data);

4.9.3. If, under the Agreement, one Party transfers the Data to the other Party, the Party transferring the Data shall be responsible for the correctness of the transferred Data and that it is entitled to transfer the Data to the other Party. The Party shall complement or correct the Data, terminate the processing of data transferred by the respective Party or destroy them, if the transferred Data are incomplete, outdated, false or processed illegally. The Parties undertake to store the Data received under the Agreement no longer than it is necessary for the purpose for which they were transferred, and after the goal set in the Agreement has been reached, they undertake to erase the received Data from their information systems as soon as possible;

4.9.4. The Parties agree that if any of the Parties is held liable for a breach of personal data protection committed by the other Party, the guilty Party shall, to the extent it is responsible for the breach, compensate all the costs, payments, damage, expenses or losses inflicted as a result of its act or omission.

5. PAYMENTS AND SETTLEMENT PROCEDURE

5.1. The Licensee shall make payments to the Licensor for the use of the Know-how and the Trademark as follows:

* + 1. the initial, fixed payment of a total of 1000,- EUR (one thousand euro, 00 cents), without value added tax (hereinafter referred to as VAT);
		2. interest payments in the amount of \_\_\_\_\_\_\_\_\_% of the income earned by the Licensee for each sold Genetic Test, without value added tax (hereinafter referred to as VAT).

5.2. The Licensee shall make the payment in accordance with the invoices prepared by the Licensor.

5.3. The Licensee shall pay the invoice for the initial, fixed payment specified in Clause 5.1.1 of the Agreement within 1 (one) month of conclusion of the Agreement and issuing of the invoice.

5.4. When paying regular interest payments, the Parties shall observe the following:

5.4.1. within 15 (fifteen) days of the end of each calendar half a year (June, December) the Licensee shall submit to the Licensor a written report providing a summary and details of sales and income volumes, and the amount of interest payments calculated by the Licensee and due to the Licensor. Upon the Licensor’s request, the Licensee, no later than within 15 (fifteen) days shall submit clarifications, details and supporting documents for the information included in the report;

5.4.2. The Licensor shall evaluate the received information and, if it is considered sufficient and acceptable, shall send a regular invoice for interest payment to the Licensee;

5.4.3. The payment deadline for the Licensee shall be 15 (fifteen) days of receiving the invoice issued by the Licensor;

5.5. Registration of income and provision of reports:

5.5.1. The Licensee shall keep complete and accurate records, incl. supporting documentation, of sales of Genetic Test copies and the income earned;

5.5.2. The Licensee shall submit the records and documentation on sales of the Genetic Test and income earned to the Licensor and the independent, certified auditor or accountant selected by the Licensor, or the authorities supervising the implementation of the project, having received a previous notice regarding such a wish;

5.5.3. The Licensee should keep accounting and record-keeping records together with supporting documentation for at least 5 (five) years of the end of the respective period, for which interest payment is calculated. The Licensor may request the information for 2 (two) years of termination of the Agreement;

5.5.4. Any accounting audit or audit shall be performed for the Licensor’s funds;

5.5.5. An accounting audit or audit may not be held more often than 1 (once) a year, except for the cases, when shortcomings have been stated in the previous half-a-year. In this case the audit may take place twice a year or every quarter;

5.5.6. By concluding the Agreement the Parties may clarify or supplement the conditions included in Sub-Clauses of Clause 5.5.

6. EFFECTIVE PERIOD OF THE AGREEMENT

6.1. The Agreement is concluded for 7 (seven) years and enters into force when signed by both Parties.

6.2. The Parties are entitled to terminate the Agreement before its expiry in accordance with a written agreement between the Parties.

6.3. If any Party violates any provision of the Agreement and such a violation is not rectified within 30 (thirty) working days of receiving a written notice of the other Party, or if the violation reoccurs, the other Party may terminate the Agreement unilaterally. The Party terminating the Agreement should notify the violating party, why and when the Agreement is terminated. The other Party shall send the notice including the justification and date of termination of the Agreement to the party in default no later than 30 (thirty) days before the day of termination of the Agreement.

6.4. The Licensor is entitled to terminate the Agreement unilaterally also in case, if:

6.4.1. the Licensee does not pay the initial, fixed payment within the set deadline;

6.4.2. it is discovered that the Licensee provided false information within the scope of the auction, which granted it the right to conclude the Agreement;

6.4.3. if insolvency proceedings or legal protection proceedings (out-of-court legal protection) of the Licensee are initiated in the case;

6.4.4. the Licensee’s economic activity is suspended for more than 2 (two) weeks;

6.4.5. international or national sanctions or serious sanctions affecting interests of the financial and capital market imposed by member states of the European Union or the North Atlantic Treaty Organization are applied to the Licensee during the effective period of the Agreement;

6.4.6. the Licensee has violated the provisions of Confidential Information or trade secret;

6.4.7. Within 2 (two) years, not counting the first year after the conclusion of the Agreement, the Licensee does not ensure the performance of the Genetic Test at least 40 (forty) times per year in average. In this case, the Parties shall first search for solutions through negotiations.

6.5. In the event of any termination of the Agreement the Licensee shall:

6.5.1. Pay the Licensor the payments, which have not been made yet, but which are due. Such payments also include interest payments for the period, when there the Licensee had actual income from the sale of the Genetic Test, but since the half-a-year reporting period has not completed, they were not calculated and paid to the Licensor;

6.5.2. Stop any use of the Know-How and the Genetic Test immediately;

6.5.3. In accordance with Clause 4.7 of the Agreement, return to the Licensor all information and materials qualifying as Confidential information and commercial information;

6.6. When the 7 (seven) year period of the Agreement is over, if the Licensee has fulfilled its liabilities under the Agreement, the Licensee shall have pre-emptive right to obtaining the license for another 7 (seven) year period by concluding a new agreement or additional agreement to this Agreement, and providing for License fee payments. In this case, the License fee, at the choice of the Parties, may be determined as a specific payment for each sold Genetic Test unit.

7. LIABILITY OF THE PARTIES AND DISPUTE SETTLEMENT PROCEDURE

7.1. The Licensee shall pay the Licensor for a payment delay a penalty of 0.5 (zero point five) % of the outstanding payment amount for each day of delay but not more than 10 (ten) % of the delayed amount.

7.2. The payment of the penalty shall not release the Parties from complete fulfilment of their liabilities.

7.3. The Parties are bound by generally acceptable force majeure conditions, which may be caused by fire, natural calamities, war, blockades, regulatory enactments imposed by the state and preventing performance or other condition not subject to the will and control of the Parties. If these circumstances continue for more than 3 (three) months, then each of the Parties is entitled to terminate the Agreement unilaterally, and in this case none of the Parties is entitled to demand from the other Party the losses related to termination of the Agreement or covering of losses. However, the Parties are bound by provisions of Clause 6.5 of the Contract.

7.4. The Party facing force majeure shall inform the other Party about its occurrence and termination in writing within 5 (five) calendar days. To ascertain the existence of such conditions and their duration, the other Party may request official statements issued by the respective state authority, or other proof.

7.5. The Parties undertake responsibility for partial or full default of provisions of the Agreement in accordance with the Agreement, the Civil Law and other regulatory enactments.

7.6. Any disputes, which arise between the Parties during its effective period of this Agreement, shall be resolved thorough negotiations. If no agreement is reached within 30 (thirty) calendar days, the disputes shall be settled in the manner prescribed by regulatory enactments.

7.7. The Parties shall compensate each other for any losses inflicted by their act or omission.

8. FINAL PROVISIONS

8.1. Any matters not reflected in the Agreement shall be viewed in accordance with applicable regulatory enactments of the Republic of Latvia.

8.2. If any Clause of this Agreement loses its legal effect, this shall have no effect on the validity of other Clauses of the Agreement.

8.3. Any supplements, corrections and amendments to the Agreement shall have legal force, when executed in writing and signed by both Parties, thus becoming an integral part of the Agreement.

8.4. Any written information relating to the Agreement (including sent electronically) is binding on both parties, and may serve as evidence, if necessary, if the Party, who has sent information received a confirmation from the other Party that the information has been received.

8.5. The contact person in the performance of the Agreement with a delegation to contact the contact person of the other Party in any matters related to the performance of the Agreement, including preparation and signature of statements, coordination of reports, invoices and performance of other liabilities arising from the Agreement on behalf of the Parties, except signing of amendments to the Agreement:

- on behalf of the Licensor should be \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, tel. \_\_\_\_\_\_\_\_\_\_\_\_, e-mail address: \_\_\_\_\_\_\_\_\_\_\_\_,

- on behalf of the Licensee should be \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, tel. \_\_\_\_\_\_\_\_\_\_\_\_, e-mail address: \_\_\_\_\_\_\_\_\_\_\_\_,

informing the other party, in case of changes in personnel.

8.6. The Agreement is concluded in Latvian on \_\_ (\_\_\_\_) pages, not including Annexes as an electronic document. The Parties have access to the Agreement signed by both parties in the electronic format. At the time of conclusion, the Agreement has the following annexes:

* Annex 1 – \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,
* Annex 2 – \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

9. DETAILS AND SIGNATURES OF THE PARTIES

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| --- | --- |
| Licensor**:****Rīga Stradiņš University**Reg. No. 90000013771Address:Dzirciema iela 16, Riga, LV-1007Bank: A/S “Swedbank”SWIFT:  HABALV22Account: LV02HABA0551000376050Bank: A/S “SEB banka”SWIFT: UNLALV2XAccount: LV28UNLA0050013752619PositionName Surname*(Indicate as needed)*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature) | **Licensee:****\_\_\_ “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”**Reg. No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Bank: A/S “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”SWIFT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Account:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PositionName Surname*(Indicate as needed)*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(signature) |

THE DOCUMENT HAS BEEN SIGNED WITH A SECURE ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP