PRÁVNÍ DDĚL NÍI EM
Registr
číslo 773/21

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DONOR HLA TYPING SERVICE AGREEMENT

From

Histogenetics, LLC., with its registered office at 300 Executive Blvd., Ossining, NY 10562, USA, represented by MD CEO & Co-Founder (hereinafter referred as "HistoGenetics" or "supplier") to

The Institute for Clinical and Experimental **Medicine**, an organization co-funded by the state, foundation charter No. 17268-II/2012 of 29 May 2012, with its registered office at Vídeňská 1958/9, 140 21 Prague 4 – Krč, Postal code, 140 21, Czech republic, ID No.:00023001 VAT no.: CZ00023001 represented by Ing. Michal Stiborek, MBA, director (hereinafter referred as "**IKEM**" or "**client**")

(together also as "Parties" or individually as "Party")

WHEREAS, HistoGenetics is an Independent private Company that is specialized in HLA typing by DNA sequencing (SBT) using most current technologies.

WHEREAS, IKEM is the largest specialised clinical and science & research institute in the Czech Republic focused on the fields of cardiovascular diseases, organ transplants, diabetology and metabolism disorders.

NOW, THEREFORE, in consideration of the following mutual promises, covenants, and conditions and any sums to be paid, the parties hereto agree to conclude Donor HLA typing service agreement (hereinafter referred as "Agreement")

SUBJECT OF THE AGREEMENT

The subject of this Agreement is provision of the services from the supplier consisting of small-scale public procurement is HLA typing of hematopoietic stem cell donors in resolution set by the client from samples of blood, saliva, or buccal swabs by next generation sequencing (NGS) on Illumina MiSeq platform or similar and provision of sample testing result in required electronic format (hereinafter referred as "Services") on one side and obligation of the client to pay agreed price for provided service on the other side upon the conditions stated in this Agreement.

1. Volume, Loci, Resolution level, Pricing, and Partners

- 1.1. Volume of samples is not limited.
- 1.2. DNA will be extracted by supplier at no extra charge.
- 1.3. HistoGenetics will perform HLA- A, B, C, DRB1, DQB1, DPB1 typing using Illumina MiSeq NGS platform + PacBio platform to accomplish at least "g" level resolution on all the client samples.
- 1.4. \$20.00 per sample for HLA-A. B, C, DRB1, DQB1, DPB1 typing with "g" level NGS resolution.

1.5. The price per sample is including VAT and covers all costs including delivery of results.

2. Sample type, delivery, and invoicing

- 2.1. The samples will be delivered to HistoGenetics by courier from IKEM.
- 2.2. HistoGenetics would accept blood, buccal swabs, saliva, or filter papers. Samples could be stored at HistoGenetics upon client's request and shall be destroyed at client's request as well.
- 2.3. HistoGenetics shall invoice to client all Services provided and work performed on monthly basis.
- 2.4. Payments will be made by wire transfer to the suppliers' account based on tax documents (invoices) issued by the supplier which will be due in thirty (30) calendar days from the date of invoice delivery to the client invoice address: Vídeňská 1958/9, 140 21 Prague 4 Krč, Postal code, 140 21 email:
- 2.5. The supplier's invoices must be of a form and content compliant with the requirements of Act. No. 536/1991 Coll. Accounting Act as amended and must contain all particulars of a tax document pursuant to Section 29 of Act No. 235/2004 Coll. VAT Act as amended. Supplier undertakes to indicate the banking institution and bank account number as published by a tax administrator and in favor of which the payment is to be made.
- 2.6. The client may return an invoice if it does not contain all the above-specified particulars. In such case, the agreed maturity period commences as of the delivery of a corrected invoice to the client invoice address.
- 2.7. Supplier may only assign his financial claims from the client incurred in connection with this Agreement to a third party subject to the client's prior written consent.

3. Statement of Work and Reporting Specifications

- 3.1. Turn-around time for 90% of results is twenty-one (21) calendar days from delivery of samples from client to the supplier's laboratory.
- 3.2. HistoGenetics agrees to update to the latest version of the allele database six (6) calendar months after release.
- 3.3. Results will be provided to client from supplier in electronic format HGX and Excel structured as requested by client and available for download either in secure storage or in other way which allows secure transfer of data to client from supplier.
- 3.4. Place where the typing results will be delivered is as follows: IKEM, Czech Stem Cells Registry, Vídeňská 1958/9, 140 00 Prague 4, Czech republic, Europe.
- 3.5. HistoGenetics is strongly committed and recognized as a laboratory with a high-quality level. HistoGenetics holds accreditation with ASHI for HLA registry typing and donor/patient typing at high resolution using PCR-SBT. HistoGenetics must maintain its ASHI certification current and valid through the whole term of this Agreement current valid version is attached to this Agreement as Annex 1. HistoGenetics also maintains New York State License and CLIA registration, which is attached to this Agreement as Annex 2 and Annex 3. CLIA inspected HistoGenetics last week and found no fault or deficiency in our operation based on CLIA standards.
- 3.6. HistoGenetics will inform IKEM immediately if the ASHI accreditation of HistoGenetics has expired.

4. Term and Termination

- 4.1. This Agreement will become valid on the date on which it is last signed by the authorized representatives of the Parties and will become effective by publication in the register of contracts pursuant the Act No. 340/2015 Coll., on the Register of Contracts as amended (the "Effective Date") and is concluded for the duration of 24 months.
- 4.2. IKEM will be responsible for its own logistics and financial obligations connected with the fulfillment of the obligations in accordance with this Agreement.
- 4.3. This Agreement may be terminated by the client without the cause upon one-month prior written notice which shall be delivered to the supplier on the postal address stated un the headings of the Agreement whereupon termination period shall started first day of the calendar month following the month of the delivery date of the termination notice to supplier. This Agreement may be terminated by written notice with immediate effect in the event of but not limited to; by IKEM in the event of the suspension or revocation of the ASHI accreditation of HistoGenetics, or by either party upon insolvency or bankruptcy of the other Party.
- 4.4. Fulfillment of the provided Services by supplier must be in compliance with all applicable rules.

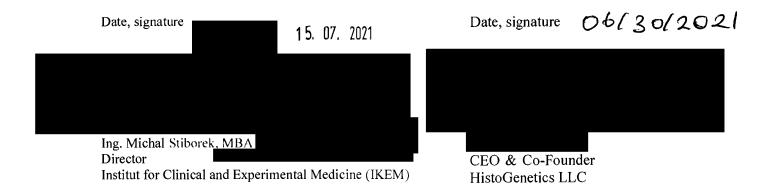
5. Miscellaneous

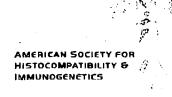
- 5.1. HistoGenetics stores material from all donors to perform other tests if requested by Customer. The owner of the samples is IKEM. Upon Customer's request, HistoGenetics must release the samples and prepare them for shipping.
- 5.2. HistoGenetics will fulfill the EU GDPR and other relevant data protection standards by using Microsoft based tools that ensure compliance with GDPR. HistoGenetics will work with external audit companies to ensure GDPR standards are implemented and functional at HistoGenetic.
- 5.3. Orders and electronic result reporting are processed as currently agreed upon.
- 5.4. This Agreement sets forth the entire agreement between the Parties and supersedes all previous agreements, written or oral, regarding the subject matter hereof. This Agreement may be amended only by an instrument of amendments in writing duly executed on behalf of the both Parties.
- 5.5. The invalidity of any provision of this Agreement or any loophole in this Agreement shall not affect the validity of any other provision hereof. The Parties undertake to replace the invalid provision or close the loophole in the Agreement with another provision which reflects legally the originally intended commercial objectives of the Parties as closely as possible.
- 5.6. This Agreement has been executed in English and in Czech. The Parties hereto agree that the Czech version shall prevail; this includes prevalence over the codes of conduct of the applicable professional and industrial associations for all matters of interpretation.
- 5.7. This Agreement shall be construed in accordance with and governed exclusively by the laws of the Czech Republic, without reference to its rules of conflict of law. In the event of any controversy or claim arising out of or relating to any provision of this Agreement, the Parties shall first try to settle those conflicts amicably between themselves. All disputes arising in connection with this Agreement, which cannot be settled amicably, shall be exclusively settled by the general competent courts of the Czech Republic.
- 5.8. Neither Party may not assign this Agreement nor assign any of its rights under this Agreement, except with the prior written consent of the other Party.

- 5.9. Failure on the part of any Party, in any or more than one instance, to insist upon the performance of any of the terms, covenants, or conditions of this Agreement or to exercise any right or privilege contained within this Agreement, or the waiver by any Party of any breach of any of the terms, covenants, or conditions of this Agreement shall not be construed as thereafter waiving any such terms, covenants, conditions, rights, or privileges, but the same shall continue and remain in full force and effect, as if no such forbearance of waiver had occurred.
- 5.10. This Agreement may be executed in two counterparts each of which is deemed an original and all of which constitute one and the same agreement.
- 5.11. Neither Party will be responsible for or liable to the other Party for non-performance or delay in performance of any terms or conditions of this Agreement due to acts or occurrences beyond the reasonable control of the nonperforming or delayed party. Such causes include, but are not limited to, acts of God, acts of government, embargoes, terrorism, wars, riots, strikes or other labor disputes, shortages of labor or materials, hurricanes, fires, floods, or any other circumstances of like character. The Party whose performance is delayed or prevented shall promptly provide to the other Party written notice of the existence of and the reason for such non-performance or delay, and shall work diligently to mitigate its effects and make best efforts to resume performance as soon as practicable.
- 5.12. The headings in this Agreement are for the convenience of reference only and are not substantive parts of this Agreement nor shall they affect its interpretation.
- 5.13. Annexes to this Agreement:

Annex 1: ASHI certification
Annex 2: New York State License
Annex 3: CLIA registration

IN WITNESS WHEREOF, the Parties have executed this Agreement in three originals by their duly authorized representatives.





Accreditation Office 1716 Field Avenue St. Paul, MN 55116

Augi	ıst	22.	20	19

August 22, 2019
The Histogenetics Laboratory, Inc. 300 Executive Blvd. Ossining NY 10562
RE: ASHI Accreditation No. 03-1-NY-26-2 CLIA No. 33D0985173
Dear and and an area and an area and ar
I have received and reviewed all of the materials sent to me by, your ASH Commissioner, in regards to your recent inspection by and and I am in agreement with the recommendations of your Commissioner that your laboratory has successfully demonstrated compliance with all mandatory ASHI Standards.
On the basis of the recommendations from your Commissioner, The Histogenetics Laboratory, Inc., 03-1-NY-26-2, under direction of and Nezih Cereb, MD, is granted re-accreditation for the following Testing Categories:
Areas of Accreditation:

Categories & Systems:

HLA Typing Class II: Molecular HLA Typing Class I: Molecular Next Generation Sequencing

Histocompatibility Testing For Other Clinical Purposes

HSC/BM Transplantation: Related Donor HSC/BM Transplantation: Unrelated Donor

Accreditation for the above areas of accreditation, categories, and systems will be valid until 8/31/2021, pending successful completion of an interim, self-cycle next year.

Your laboratory is accredited by ASHI for the following CMS subspecialties: Histocompatibility Testing.

You and your laboratory staff are to be commended for maintaining ASHI's high standards for laboratory performance and patient service.

Should you have any questions about the inspection or accreditation process, please contact the appropriate commissioner or the ASHI Accreditation Office at (651) 202-3637.



New York State Department of Health

Clinical Laboratory Permit

CLIA: 33D0985173

Histogenetics

300 Executive Blvd Ground Fl

Ossining NY 10562

Histogenetics LLC Owner:

is hereby authorized to perform laboratory procedures at the above location in the following permit shall become void upon a change in the director, owner or location of the laboratory, categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This and an application for a new permit shall be made to the Department.

Non-Malignant Leukocyte Immunophenotyping Cellular Immunology

Transplant Monitoring Histocompatibility

EUA-approved molecular methods) (limited to COVID-19 tests using

Renewal

Effective Date: July 1, 2020

Expiration Date: June 30, 2021

Permit Not Transferable Subject to Revocation



ASHIM FOR HISTOCOMPATIBILITY AND IMMUNOGENETICS

CERTIFIES THAT

The Histogenetics Laboratory, Inc.

03-1-NY-26-2

33D0985173 CLIA#

UNDER THE DIRECTION OF



HAVING MET ALL APPLICABLE STANDARDS AND THE REQUIREMENTS OF THE SOCIETY, IS GRANTED ACCREDITATION

From: 9/1/2019

To: 8/31/2021

Assuming all interim requirements are met, In the following areas:

Histocompatibility Testing for Other Clinical Purposes HSC/BM Transplantation: Related Donor

ACCREDITATION PROGRAM DIRECTOR

HSC/BM Transplantation: Unrelated Donor

Accompliation done not automatically transfer when a chance in numeratin director or location has nonumed