

Cell Line Information Pack (CLIP)

Cell line name

YUi017-A



Purpose

The purpose of this Cell Line Information Pack (CLIP) is to communicate cell line specific information to potential users of the cell line, and to confirm that a User has received it upon the purchase of an EBiSC cell line.

Information

The CLIP may provide a variety of types of information related to an individual cell line. Of particular importance are Third Party Obligations (TPOs), which are ethical or legal obligations of a Depositor related to the use of the cell line. TPOs may impose ethical or legal limitations on the ability of a User to use the cell line, or require steps to be taken before it can be used. TPOs are likely to be:

- Obligations under license to an intellectual property rights (patent) holder, or
- Restrictions on use imposed by the donor of the primary tissue from which the cell line was made.

Third Party Obligations: donor consent provisions

None.

Third Party Obligations: IP or license provisions

iPS-AJ: This EBiSC Cell line was generated under the technology disclosed in patents related to iPS cells which are owned by Kyoto University and are licensable from iPS Academia Japan., Inc. ("iPS AJ"). Commercial user (for-profit entity) acknowledges that, prior to receipt and use of this EBiSC Cell line, such commercial user needs to have an appropriate patent license from iPS AJ even for its research use. Academic user (academic or not-for-profit entity) acknowledges that such academic user does not need a patent license from iPS AJ for its research use, provided, however, that when such academic user uses this EBiSC Cell line for other than its independent research use, such academic user acknowledges that the academic user might need to obtain an appropriate patent license from iPS AJ. For inquiries to iPS AJ, please contact at license@ips-ac.co.jp.

The Foundation for Angelman Syndrome Therapeutics (FAST) is the patient advocacy organization working to cure Angelman syndrome (AS) and supported generation of this iPSC line. As the largest funder of Angelman syndrome research in the world, our goal is to bring safe and effective treatment into current medical practice as quickly as possible. To do this, we: set the agenda for the therapeutic landscape for AS and help to accelerate it, from funding promising research at the academic level all the way to starting companies; create the necessary infrastructure outside of drugs and their development, from projects like our global registry and newborn screening to preparing for regulatory approval processes and advocating for insurance coverage; and we activate and educate those in the worldwide AS community interested in and committed to clinical trials, and what the future of drug development will be for our loved ones. For additional information, please visit www.cureangelman.org or if you would like to contact FAST, please send an email to info@cureangelman.org.

Extensive Longitudinal caregiver reported data is available through the Global Angelman Syndrome Registry, further details are available at <https://www.angelmanregistry.info/> and data requests can be made by emailing curator@angelmanregistry.info

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Limited use label License No: 518 CytoTune™ Technology for Products

Notice to Purchaser: This product is authorized for reprogramming methods that involve or pertain to the preparation of iPS cells or related cells. The purchase of this product conveys to the purchaser the limited, non-transferable right to use the purchased amount of product to perform internal research and for educational purposes.

This product or any of its components, or iPS cells generated by use of the product, or progeny (including those genetically engineered)/modifications (partially or fully differentiated cells) thereof (hereafter "Materials") shall not be administered to – (a) human subjects, including for human clinical use and/or to (b) animals for veterinary use (i.e., not for research) – for therapeutic, diagnostic or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation and/or regenerative medicine, nor shall be used for the creation of human embryos, and/or admixed embryos with embryos of animals including humans for any purpose including for research. No right to resell the Materials is conveyed expressly, by implication, or by estoppel.

For clarity, purchasers have the right to use third party service providers for generating iPS cells and modifications for the benefit of such purchasers, but not for screening using the Materials except when such a provider has appropriate licenses from ID Pharma Co., Ltd. and iPS Academia Japan, Inc. Purchasers can deposit the Materials with not-for-profit repositories ("Repositories") and transfer cells to not-for-profit research entities (not affiliated with a for-profit organization) for their internal research. Such recipient Repositories and not-for-profit research entities are allowed to distribute the Materials not-for financial gain to other users for their internal research, and in case the recipient user is a for-profit entity, such recipient Repositories and not-for-profit research entities shall notify the recipient user that such for-profit entity is required to contact iPS Academia Japan, Inc., which notification shall be fulfilled by transferring a copy of this Label License along with the transferred Materials.

The limited right allowed in paragraphs above does not include the following commercial applications:

- i. use of iPS cells and progeny (but not modifications) for manufacture or quality control of any product;
- ii. use of the Materials to provide services including:
 - a) generation of the Materials, information or data on behalf of a third party for financial gain and
 - b) screening on behalf of purchasers for financial gain;
- iii. use of the Materials by purchasers for screening or later stage development of therapeutics, diagnostics, prophylactics (e.g., hit-to-lead, lead optimization), except when performed by or on behalf of a not-for-profit research entity for internal research and not for financial gain;
- iv. sale of the Materials to third parties.

To obtain commercial rights for above commercial applications (i) through (iv), purchasers are requested to contact ID Pharma Co., Ltd. at info@idpharma.jp and Academia Japan, Inc. directly at license@ips-ac.co.jp or through ID Pharma Co., Ltd.

Notwithstanding the foregoing, the following activities are not considered commercial applications for purposes of this label license:

- (a) basic research, including, without limitation, target discovery, target validation and assay development;
- (b) transfer of cells to not-for-profit research entity for its internal research not for financial gain;
- (c) compound screening and safety testing for development of therapeutics, diagnostics and prophylactics by academic and not-for-profit research entities for their non-commercial internal research;
- (d) license or commercialization of research results except where such results are drugs or drug candidates, iPS cells or modifications, or where such license or commercialization uses iPS cells or progeny;

Other than rights granted herein, no other right, express or implied, is conveyed by the sale of this product.

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Notice: If the Materials are transferred to third parties including Repositories in accordance with the terms of this label license accompanying the Materials (hereafter "Label License"), the transferring party should notify recipients of such Materials of these terms by transferring a copy of the Label License to the recipients.

Data Processing

The Personal Data which can be Processed in view of this EAUA are

- Genetic Data including STR profiles: Yes
- Clinical Data: No
- Biometric Data: No
- Other: No

The categories of the Data Subjects to which the Personal Data relate that are Processed are

- Study participants: Yes
- Other:

The nature and the purpose of the Processing of the Personal Data are as follows:

Collecting / storing / analysing / characterisation / qualification / use / distribution of iPSC lines / and iPSC derivatives

Other information

Any publications or public dissemination of results using EBiSC iPSCs should be accompanied by the following acknowledgement: "The EBiSC Bank acknowledges Yale University / FAST as the source of the human induced pluripotent cell line YUi017-A which was generated with support from the EBiSC2 project. The EBiSC has received support from the Innovative Medicines Initiative (IMI) Joint Undertaking (JU) under grant agreement n°115582 and from the IMI-2 JU under grant agreement No 821362, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013), European Union's Horizon 2020 research and innovation programme and EFPIA."

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SIGN AND RETURN THIS DOCUMENT WITH YOUR COMPLETED ACCESS AND USE AGREEMENT

User acknowledgement

Please sign below to indicate that you have read and acknowledge the information contained in this CLIP.

Name _____ Position _____

Signature _____ Date _____



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