Certificate of Analysis

Cellartis® Human iPS Cell Line 22 (ChiPSC22)

Catalog No.	Amount	Lot Number
Y00320 (Not sold separately) Sold as a part of Y00325	1 vial	Specified on product label

Description

Cellartis Human iPS Cell Line 22 (ChiPSC22) contains human induced pluripotent stem (hiPS) cells frozen as a single-cell suspension (≥1.5 x 10^6 viable cells/vial). Prior to cryopreservation, the cells were cultured using the Cellartis DEF-CS™ 500 Culture System (Cat. No. Y30010). Cellartis Human iPS Cell Line 22 (ChiPSC22) is sold as a part of the Cellartis Human iPS Cell Line 22 (ChiPSC22) Kit, which also contains the Cellartis DEF-CS 100 Culture System − a complete system optimized for hiPS cell cultures. The Cellartis DEF-CS 500 Culture System should be purchased separately for continued culturing of Cellartis hiPS cell lines.

Package Contents

- 1 vial of Cellartis Human iPS Cell Line 22 (ChiPSC22) (≥ 1.5 x 10^6 viable cells/vial)

Storage Conditions

- Store cells at –150°C or –196°C (liquid nitrogen vapor phase)

Shelf Life

- 1 year from date of receipt under proper storage conditions

Storage Medium

- STEM-CELLBANKER® (Zenoaq Resource Co. Ltd., Cat. No. ZR636)

Shipping Conditions

- Dry ice (–70°C)

Product Documents

Documents for Takara Bio Europe AB products are available for download at **www.takarabio.com/manuals**
The following document applies to this product:

- Cellartis Human iPS Cell Lines User Manual

Cell Type Information

Derivation

Human skin fibroblasts have been reprogrammed using defective polycistronic retrovirus technology combined with *Oct-4, SOX-2, KLF-4,* and *c-Myc*. The cell line origin has been confirmed by cell line authentication. The cells have been tested and are negative for the presence of recombinant competent retroviruses by reverse transcriptase activity assay, which confirms the absence of replication-competent retroviruses in culture.

The hiPSC derivation process at Takara Bio Europe AB follows all applicable laws in Sweden and EU and is approved by the EudraCT and the French Ethics Committee (CPP ICF XI/ Les Comités de protection des personnes (CPP)).

Takara Bio Europe AB.
A Takara Bio Company
Arvid Wallgrens backe 20, SE-413 46 Göteborg, Sweden
Technical Support: techEU@takarabio.com

United States/Canada 800.662.2566 | Asia Pacific +1.650.919.7300 | Europe +33.(0)1.3904.6880 | Japan +81.(0)77.565.6999

(111518)

Donor

Skin fibroblasts from a human 32-year-old adult male (European/North African), healthy volunteer (74 kg/179 cm).

The tissues used by Takara Bio Europe AB for the reprogramming of somatic cells into hiPSC are from donors who have signed informed consent which outlines in detail the purpose of the donation and the procedure for processing of the donated tissue. In order to protect the privacy and the confidentiality of the donors, all identifiers associated with the donors have been removed. The donor consent was obtained for commercial use. Notably, the donation did not result in any financial gain for the donors.

HLA typification data

HLA-A*02:01
HLA-B*07:02, HLA-B*40:01
HLA-C*03:04, HLA-C*07:02
HLA-DRB1*13:02, HLA-DRB1*14:01
HLA-DQB1*05:03, HLA-DQB1*06:04
HLA-DPB1*03:01, HLA-DPB1*04:01

Recommended Cell Culture Medium and Coating Substrate

Cellartis Human iPS Cell Line 22 (ChiPSC22) should be used with the Cellartis DEF-CS 500 Culture System (Cat. No. Y30010), which contains coating substrate, additives, and basal medium for optimal culture of pluripotent cell lines. Using other coating substrates or mediums may require optimization by the customer. Keep thawed Cellartis Human iPS Cell Line 22 (ChiPSC22) at 37°C ±1°C, 5% CO_2, and >90% humidity.

Safety Precautions

Cellartis Human iPS Cell Line 22 (ChiPSC22) contains human source material and should be treated as potentially infectious. Discard cell-contaminated materials according to local regulations.

Wear suitable protective clothing, safety glasses, and gloves when handling liquid nitrogen.

Additional Notes

The cells are frozen as a single-cell suspension.

Quality Control Data

Functional Tests

Each lot of Cellartis Human iPS Cell Line 22 (ChiPSC22) has been tested for thaw recovery, morphology, growth rate, karyotyping, expression of pluripotency markers (OCT-4, TRA-1-60, TRA-1-81, and SSEA-4), and absence of a differentiation marker (SSEA-1).

Mycoplasma Contamination Test

Each lot of Cellartis Human iPS Cell Line 22 (ChiPSC22) has been tested and found to be free of *Mycoplasma* contamination.

Bacterial and Fungal Contamination Test

Each lot of Cellartis Human iPS Cell Line 22 (ChiPSC22) has been tested and found to be free of bacterial and fungal contamination.

Human Viral Contamination Test

The primary cell line used to establish this product has been verified to be negative for human viruses (HBV, HCV, HIV1, HIV2, HTLV1, and HTLV2).

Certificate of Analysis

Cat. No. Y00320

Cellartis® Human iPS Cell Line 22 (ChiPSC22) (Not sold separately)

Sold as a part of Y00325

Notice to Purchaser

This product is for research use only. It is not intended for use in therapeutic or diagnostic procedures for humans or animals. Also, do not use this product as food, cosmetic, or household item, etc.

This product may not be resold or transferred, modified for resale or transfer, or used to manufacture commercial products without written approval from Takara Bio Europe AB.

If you require licenses for other use, please contact us by phone at +46.(0)31.758.0900.

Your use of this product is also subject to compliance with any applicable licensing requirements as detailed below, in our catalogues, on our website at http://www.takarabio.com, on the label or other documentation accompanying the goods. It is your responsibility to review, understand and adhere to any restrictions imposed by such statements.

STATEMENT C005

This product is manufactured and sold by Takara Bio Europe AB based on a license to Cellectis SA. The use of this product is strictly limited to purchaser's own internal research, including basic research, drug discovery research up to and including IND-enabling preclinical toxicological studies or equivalents thereof, excluding any use in the T-cell field. Purchaser cannot have any right to use this product or its components in humans for any purposes including but not limited to diagnostics and/or therapeutics, or otherwise clinical trials. Purchase does not include any right to resell or transfer this product to a third party regardless of whether or not compensation is received. Purchasers wishing to use this product for purposes other than internal research use should contact us. No express or implied license is granted to the purchaser.

STATEMENT C006

For **Not-For-Profit Entities**, the purchase of this product grants to the purchaser, a non-exclusive, non-transferable, non-sublicensable and limited license to use this product for internal, non-commercial, scientific research use only. The license specifically excludes the right to sell or otherwise transfer this product, its components or derivatives thereof to a third party, regardless of whether or not compensation is received. The license does not grant any right for the purchaser to use this product or its components in humans for any purposes including but not limited to diagnostics and/or therapeutics, or otherwise clinical trials. Purchasers wishing to use this product for purposes other than internal research use should contact us. No express or implied license is granted to the purchaser.

For-Profit Entities wishing to use this product are required to obtain a license from Takara Bio Europe AB. For license information, please contact us by phone: +46.(0)31.758.0900 or e-mail: info-cellartis@takarabio.com.

For-Profit Entities in North America wishing to purchase this product are required to submit a completed copy of the Human iPS Cell Line license agreement to US. For details please contact licensing@takarabio.com

STATEMENT L44

This product is covered by one or more claims of the issued patents and pending patent applications: U.S. Patent Nos. 8,048,999, 8,058,065, 8,129,187, 8,211,697, 8,257,941, 8,278,104, 8,530,238, 8,900,871, 8,927,277, 8,951,801, 9,213,999, 9,404,124, 9,499,797, 9,677,141 and 9,714,433, and foreign counterparts thereof, including their divisions, continuations, extensions, substitutions, and those claiming priority therefrom or those claiming the same priorities therein.

This product is manufactured and sold by Takara Bio Inc. based on a patent license from iPS Academia Japan, Inc. The use of this product is strictly limited to purchaser's own internal research. Purchaser cannot have any right to use this product or its components in humans for any purposes including but not limited to diagnostics and/or therapeutics, or otherwise clinical trials. Purchase does not include any right to resell or transfer this product to a third party regardless of whether or not compensation is received.

The use of iPSCs generated by this product is not allowed for the purposes of the intended use as described below: 1) Creation of a human clone through transplantation of iPSCs-derived embryos into human or animal individuals, 2) iPSCs transplantation into human embryos, 3) iPSCs transplantation into human fetuses, and 4) Production of human embryos using iPSCs-derived germ cells.

Purchasers wishing to use this product for purposes other than internal research use should contact us. No express or implied license is granted to the purchaser. Any use of this product for Commercial Purposes requires a patent license from iPS Academia Japan, Inc. "Commercial Purposes" means at least one of following activities including the use of iPSCs generated by this product: 1) Use for manufacture of related products for sale including but not limited to culture medium or equipment, 2) Use in order to provide a service to a third party (including use of the differentiated cells from iPSCs), 3) Use for screening compounds, antibodies, proteins, peptides and others in developing pharmaceuticals (including diagnostic agents) for human and/or animal use (including use of the differentiated cells from iPSCs)*, and 4) Transfer to a third party (including transfer of the differentiated cells from iPSCs). *A patent license to use of iPSCs generated by this product and the use of the differentiated cells from the iPSCs for screening compounds may also be granted from Takara Bio Inc.

TRADEMARKS