

Certificate of Analysis

Cellartis® hiPS Beta Cells (from ChiPSC22)

Catalog No.	Amount	Lot Number
Y10107 (Not sold separately) Sold as a part of Cat. No. Y10106	1 vial	Specified on product label

Description

Cellartis hiPS Beta Cells (from ChiPSC22) are beta cells derived from a human induced pluripotent stem (hiPS) cell line. The hiPS cells have been differentiated into beta cells *in vitro*, dissociated into a single cell suspension, and frozen in vials.

Package Contents

- 1 vial of Cellartis hiPS Beta Cells (from ChiPSC22) ($\geq 4.8 \times 10^6$ viable cells/vial)

Storage Conditions

- Store cells in liquid nitrogen (-196°C) or in a -150°C freezer

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 documents apply to this product:

- Cellartis hiPS Beta Cells Kits User Manual

Cell Type Information

Cellartis hiPS Beta Cells (from ChiPSC22) are pancreatic beta cells derived from Cellartis Human iPS Cell Line 22 (ChiPSC22) (Cat. No. Y00320).

Safety Precautions

Cellartis hiPS Beta Cells (from ChiPSC22) contain 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.

Takara Bio Europe AB

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Quality Control Data

Functional Tests

Cell viability is measured on the day of thawing and each vial contains >4.8 million viable cells. Insulin content (>40% insulin-positive cells) and insulin secretion (>3-fold increase of insulin secretion upon KCl addition) are analyzed on Day 14 post-thawing using flow cytometry and ELISA, respectively.

Mycoplasma Contamination Test

Cellartis hiPS Beta Cells (from ChiPSC22) have been tested and found to be free of *Mycoplasma* contamination.

Bacterial and Fungal Contamination Test

Cellartis hiPS Beta Cells (from ChiPSC22) have 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).

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.

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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

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STATEMENT L67

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. and/or its affiliate(s) based on a patent license from iPS Academia Japan, Inc.

No express or implied license is granted to the purchaser.

"Product" means the differentiated cells manufactured and sold by Takara Bio Inc.

"Internal research purpose" means the use of this Product as a tool of internal research for the sole benefit of the purchaser or purchaser's contract research customer, (including screening of compounds, antibodies, proteins, peptides and others in developing pharmaceuticals (including diagnostic agents) for human and/or animal use), provided, however, that the following activities using this Product are strictly prohibited and expressly excluded from Internal research purposes;

With the exemption for academic and non-commercial clinical research done by non-profit institutions;

- 1) Administration of this Product to humans.
- 2) Use of this Product for the diagnostic testing, prevention, or treatment of human and/or animal diseases.
- 3) Use of this Product in studies involving administration to humans for cell therapy, regenerative medicine etc.

Purchaser may use this Product for its own Internal research purposes.

Purchaser shall not use the Products for its commercial purposes.

Notwithstanding the foregoing, the purchaser of this Product may provide third parties with contract research services by using this Product only for such third party's Internal research purposes.

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