# Certificate of Analysis



# Cellartis® Definitive Endoderm Cells (from ChiPSC18)

Catalog No. Amount Lot Number

Y10040 1 vial Specified on product label

# **Description**

Cellartis Definitive Endoderm Cells (from ChiPSC18) are human definitive endoderm (DE) cells derived from Cellartis Human iPS Cell Line 18 (ChiPSC18). The cells have been differentiated to definitive endoderm cells *in vitro*, dissociated to a cell suspension, and frozen in vials.

#### **Package Contents**

• 1 vial of Cellartis Definitive Endoderm Cells (from ChiPSC18) (≥ 6 x 10<sup>6</sup> 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

• Cell freezing medium containing 10% DMSO

## **Shipping Conditions**

• Dry ice  $(-70^{\circ}\text{C})$ 

#### **Product Documents**

Documents for Takara Bio Europe AB products are available for download at <a href="www.takarabio.com/manuals">www.takarabio.com/manuals</a> The following documents apply to this product:

- Cellartis Definitive Endoderm Cells (from ChiPSC18) User Manual
- Cellartis Hepatocyte Differentiation Kit User Manual

# **Cell Type Information**

Cellartis Definitive Endoderm Cells (from ChiPSC18) are human DE cells derived from Cellartis Human iPS Cell Line 18 (ChiPSC18) (Cat. No. Y00300; not sold separately).

## **Recommended Cell Culture Medium and Coating Substrate**

For further differentiation of DE cells into hepatocytes it is strongly recommended to use the Cellartis Hepatocyte Differentiation Kit (Cat. No. Y30050) with a recommended seeding density of 1.25 x 10<sup>5</sup> DE cells/cm<sup>2</sup>.

For other applications, DE cells can be seeded on Cellartis DEF-CS<sup>TM</sup> 500 COAT-1 (Cat. No. Y30012) or iMatrix-511 (Cat. No. T303). Thawing on other coatings might require optimization depending on the chosen application.

Keep thawed Cellartis Definitive Endoderm Cells (from ChiPSC18) at 37°C ±1°C, 5% CO₂ and ≥90% humidity.

Takara Bio Europe AB

A Takara Bio Company

Arvid Wallgrens backe 20, SE-413 46 Göteborg, Sweden

Technical Support: techEU@takarabio.com

Cellartis Definitive Endoderm Cells (from ChiPSC18)

# **Safety Precautions**

Cellartis Definitive Endoderm Cells (from ChiPSC18) 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.

#### **Additional Notes**

One vial contains 6 million viable DE cells and the cells can be seeded into any format; e.g. 96-well plates, 24-well plates, or T25 cell culture flasks.

# **Quality Control Data**

#### **Functional Tests**

Cellartis Definitive Endoderm Cells (from ChiPSC18) morphology has been evaluated and confirmed after thawing. Expression of SOX-17 and lack of OCT-4 have been confirmed by ICC.

## Mycoplasma Contamination Test

Cellartis Definitive Endoderm Cells (from ChiPSC18) have been tested and found to be free of *Mycoplasma* contamination.

## **Bacterial and Fungal Contamination Test**

Cellartis Definitive Endoderm Cells (from ChiPSC18) 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)

(081519) Page 2 of 3

Cellartis Definitive Endoderm Cells (from ChiPSC18)

### **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 C007

This product is manufactured and sold by Takara Bio Inc. and/or its affiliate(s) ("Takara") under a license from ViaCyte Inc. ("ViaCyte"). This product is covered by one or more claims of patents owned by ViaCyte, including WO2005063971, WO2006017134, WO2006071911, WO2005116073 and WO200616999, and their foreign counterparts.

The use of this product is strictly limited to purchaser's own internal research. Purchaser has no right to use this product or its components in humans for any purposes including but not limited to diagnostics, therapeutics, or clinical trials. Purchaser has no 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 Takara. No express or implied license is granted to the purchaser.

#### **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.

## **TRADEMARKS**

© 2018 Takara Bio Inc. All Rights Reserved.

All trademarks are the property of Takara Bio Inc. or its affiliate(s) in the U.S. and/or other countries or their respective owners. Certain trademarks may not be registered in all jurisdictions.

(081519) Page 3 of 3