

Certificate of Analysis

Cellartis® Enhanced hiPS-HEP (from ChiPSC12)

Catalog No.

Y10059 (Not sold separately)
Sold as a part of Cat. No. Y10133

Amount

1 vial

Lot Number

Specified on product label

Description

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells are human hepatocytes derived from a human induced pluripotent stem (iPS) cell line, Cellartis human induced pluripotent stem cell line 12 (ChiPSC12; Cat. No. Y00280). Cellartis Enhanced hiPS-HEP (from ChiPSC12) is a component of the Cellartis Enhanced hiPS-HEP v2 (from ChiPSC12) Kit (Cat. No. Y10133), which also contains the Cellartis Enhanced hiPS-HEP Thawing and Plating Kit (Cat. No. Y10132; not sold separately) and Cellartis Enhanced hiPS-HEP Long-Term Maintenance Medium (Cat. No. Y30052; not sold separately).

Package Contents

- 1 vial of Cellartis Enhanced hiPS-HEP (from ChiPSC12) ($\geq 12.3 \times 10^6$ 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

- Cell freezing medium containing 10% DMSO

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 Enhanced hiPS-HEP v2 Kit User Manual

Cell Type Information

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells are human hepatocytes derived from Cellartis human iPS cell line 12 (ChiPSC12; Cat. No. Y00280). ChiPSC12 cells were differentiated to hepatocyte-like cells *in vitro*, dissociated into a cell suspension, and frozen in vials.

Recommended Cell Culture Medium and Coating Substrate

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells are thawed and seeded with the Cellartis Enhanced hiPS-HEP Thawing and Plating Kit (Cat. No. Y10132; not sold separately) and cultured in Cellartis Enhanced hiPS-HEP Long-Term Maintenance Medium (Cat. No. Y30052). For additional required materials, please refer to the Cellartis Enhanced hiPS-HEP v2 Kit User Manual.

Incubate thawed Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells at $37^\circ\text{C} \pm 1^\circ\text{C}$, 5% CO_2 , and $\geq 90\%$ humidity.

Takara Bio Europe AB

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Safety Precautions

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells contain human source material and should be treated as potentially infectious. Discard contaminated materials according to local regulations.

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

Additional Notes

One vial contains $>12.3 \times 10^6$ viable cells. It is recommended that cells are seeded in 96- or 24-well plates.

Quality Control Data

Functional Tests

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cell morphology has been evaluated and confirmed on days 4, 12, and 19 after thawing. The cell population consists of $>90\%$ hepatocyte-like cells: cells are predominantly polygonal; partly bi-nucleated; and have distinct, white, cell-to-cell borders.

CYP activity has been determined at days 4, 12, and 19 after thawing by LC/MS of specific CYP metabolites, including acetaminophen (CYP1A), 4-OH-Diclofenac (CYP2C9), OH-Bufuralol (CYP2D6), and 1-OH-Midazolam (CYP3A). LC/MS analysis is performed at Pharmacelsus GmbH, Germany.

CYP1A activity	≥ 0.3 pmol/mg protein/min on days 4, 12, and 19
CYP2C9 activity	≥ 0.05 pmol/mg protein/min on days 4, 12, and 19
CYP2D6 activity	≥ 0.02 pmol/mg protein/min on days 4, 12, and 19
CYP3A activity	≥ 0.2 pmol/mg protein/min on days 4, 12, and 19

***Mycoplasma* Contamination Test**

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells have been tested and found to be free of *Mycoplasma* contamination.

Bacterial and Fungal Contamination Test

Cellartis Enhanced hiPS-HEP (from ChiPSC12) cells 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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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.

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

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