

Cellartis® DEF-CS™ 500 Xeno-Free GMP Grade Basal Medium (Prototype)

Catalog No(s). Y30071	Amount 500 ml	Lot Number AFXL002
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Description

Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (Prototype) is a chemically defined basal media that is free from human- and animal-derived components and is used for efficient expansion of undifferentiated human induced pluripotent stem (iPS) cells. Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (Prototype) is manufactured as a quality-assured product, according to guidelines for Good Manufacturing Practice (GMP) for Investigational Products.

The Prototype status indicates that this media has been produced under cGMP conditions and tested to meet development specifications, but lacks extended shelf-life testing (>12 months). This product is currently undergoing real-time stability studies in compliance with cGMP **guidelines** and internal policies. Once the studies are completed, the product will no longer be considered a prototype.

Package Contents

- 1 bottle Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (Prototype) (500 ml)

Storage Conditions

- Store at 4°C

Shelf Life

- Specified on product label

Shipping Conditions

- Blue ice (4°C)

Product Documents

Documents for Takara Bio Europe AB products are available for download at www.clontech.com/manuals

The following documents apply to this product:

- Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (Prototype) User Manual

Quality Control Data

Test Item	Specifications	Results
1) Sterility Testing	Negative	Negative
2) Mycoplasma Testing	Negative	Negative
3) pH	7.4 ± 0.2	7.3
4) Endotoxin Testing	< 5.0 EU/ml	0.848
5) Osmolarity	305 ± 15 mOsm/kg	315.2 mOsm/kg

Takara Bio Europe AB

A Takara Bio Company
 Arvid Wallgrens backe 20, SE-413 46 Göteborg, Sweden,
 Technical Support: tech-cellartis@takara-clontech.eu

United States/Canada 800.662.2566 (061616)	Asia Pacific +1.650.919.7300	Europe +46.(0)31.758.0900	Japan +81.(0)77.543.6116
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Quality Statements

- Cellartis DEF-CS 500 Xeno-Free GMP Grade Basal Medium (Prototype) is manufactured and tested in accordance with the following guidelines; “Standards for Manufacturing Control and Quality Control, etc. of Investigational Products (Investigational products GMP)” notified by Ministry of Health and Welfare Japan (“PFSB Notification No. 0709002, July 9, 2008”) (PFSB: Pharmaceutical and Food Safety Bureau).
- This medium contains no animal- or human-derived components.

It is certified that this product meets the above specifications

Approved by:



Manager, Quality Assurance

Takara Bio Europe AB

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 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.clontech.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 C010

This product is manufactured and sold by Takara Bio Europe AB based on a commercial agreement with Novo Nordisk A/S. The purchase of this product includes a license to use the product for the purchasers own internal research, including basic research, drug discovery research, IND-enabling preclinical studies. It also includes a limited license for Non-commercial Manufacturing of Cell-Based Products for Clinical Research **excluding the manufacturing of batches of human embryonic stem cells for direct differentiation into cells of the pancreatic lineage, including insulin-producing cells, for use in treatment of diabetes.** Purchaser cannot have any right to use this product for direct administration into humans or animals for any purposes, including but not limited to, diagnostics and/or therapeutics. 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 other purposes should contact us.

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This document has been reviewed and approved by the Takara Bio Europe AB Quality Assurance Department.