

Updated on: 14th October 2024

CERTIFICATE OF ANALYSIS

Lot#: CHF2313-HE-Z

PRODUCT DESCRIPTION

Reference: HuHECS/4-
Product: Cryopreserved Human Hepatocytes
Category: Suspension
Spheroid qualified: No
Organoid qualified: Yes

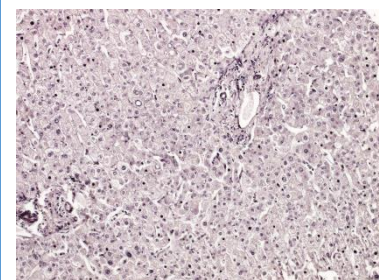
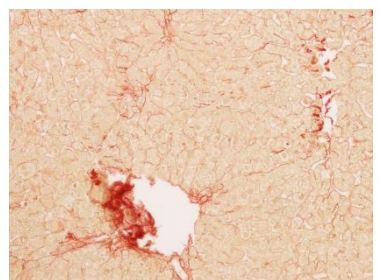
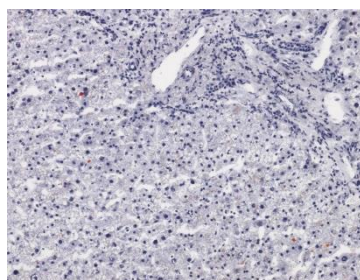
Isolation date: 26th October 2023
Initial Isolation Viability: 72.40%
Storage conditions: -196°C using LN₂
Sterility test: negative for mycoplasma, bacteria, yeast, and fungi

DONOR DEMOGRAPHICS

Species	Gender	Race	Age	BMI	Smoker	Alcohol Use	Drug Use
Human	Female	Caucasian	69	27.27	>20	Yes	No
Pathology			Serological Data ¹				
Metastatic tumor			Tested negative less than 3 months before surgery				

Patient informed consent was obtained. ¹The donor was serologically tested negative for following infectious diseases: HIV, Hepatitis B and C, and SARS-CoV-2. Donor medical history was also examined prior to accepting this donor. *For donor's medication information, please contact us.*

DONOR HISTOLOGY

Hematoxylin & Eosin staining	Sirius Red staining	Oil red staining
		

- Hematoxylin & Eosin: Parenchyma with normal appearance and with no signs of steatosis or fibrosis present.
- Sirius red: The liver has no signs of fibrosis, with only a very discrete accumulation of Sirius red staining in portal areas. Minimal matrix deposition in the sinusoidal areas.
- Oil red: No areas of steatosis with red oil staining accumulation were detected.

Conclusions: Liver in normal condition with no apparent steatosis or fibrosis.

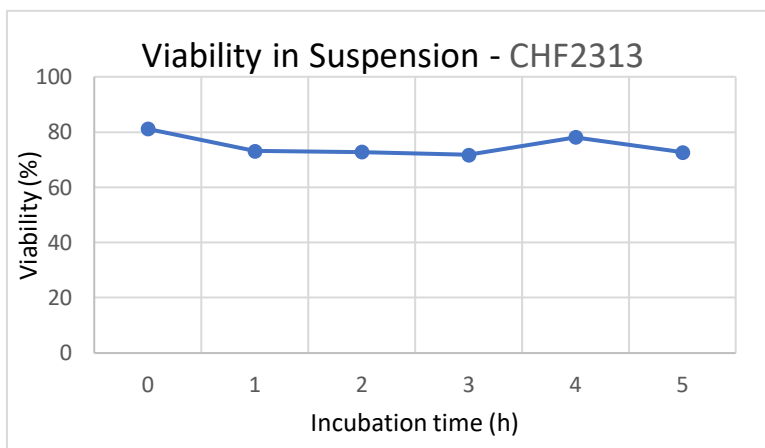
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CHARACTERIZATION FOR SUSPENSION CELLS

Post Thaw Lot information	Result	SD	n
Number of viable cells (cells/vial):	4.64x10 ⁶	± 1.12x10 ⁶	9
Post-thaw viability (%):	81.12	± 4.34	9

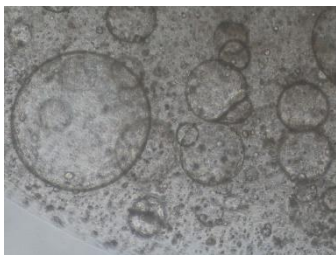
Human hepatocytes were thawed according to BeCytes Biotechnologies protocol. The post-thawing yield and viability (trypan blue exclusion assay) of hepatocytes were assessed after a purification process.

Time (h)	0	0.5	1	1.5	2	3	4	5
Viability (%)	81.12	78.70	73.15	76.85	72.82	71.78	78.07	72.66
SD	± 0.00	± 0.86	± 0.57	± 3.46	± 2.18	± 6.48	± 2.36	± 0.51



Resuspended human hepatocytes suspension (0,5 * 10⁶ cells in 0.5 ml medium) from the post-thaw assessment were incubated up to 5 h at 37°C. The assay was performed in 2 ml round-bottom tubes under shaking conditions (1000 rpm) using Eppendorf Thermomixer C. In the first two hours, samples were taken at every 30 min, after 2 h samples were taken at every 60 min. At each time point the viability of cells was calculated.

3D HEPATIC SPHEROID AND ORGANOID FORMATION

Spheroid morphology	Organoid morphology
This lot is not suitable for 3D spheroid culture according to BeCytes Technologies protocols	



Primary hepatocytes were validated for their capacity to generate liver organoids. After thawing the cells using BeCytes Technologies' thawing protocols and media, 150.000 hepatocytes were mixed with 50 µl of Matrigel® and cultured using the procedure described by Huch *et al.* (2014). For more information/protocols about 3D hepatic organoids, contact us.

If you need help for an experiment, just contact us, our experts will be pleased to assist you

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CERTIFICATION:

The viability and performance of the primary human hepatocytes provided depend primarily on the use of appropriate media and reagents, as well as the use of sterile plastics. Likewise, proper handling protocols must be followed. Please note that if these parameters are not carefully considered, the cellular response obtained in the assays may be lower than expected.

Name	Title	Signature	Cytes Biotechnologies, S.L.	Date
Pilar Sainz de la Maza	Quality Manager			14/10/24

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