Updated on: 15th February 2024

CERTIFICATE OF ANALYSIS

Lot#: CHM2314-HE-Z

PRODUCT DESCRIPTION

Reference: HuHECS/6+
Product: Cryopreserved Human Hepatocytes
Category: Suspension
Spheroid qualified: No
Specific culture requirements: No

Isolation date: 13rd November 2023
Initial Isolation Viability: 71.28%
Storage conditions: -196°C using LN_2
Sterility test: negative for mycoplasma, bacteria, yeast, and fungi

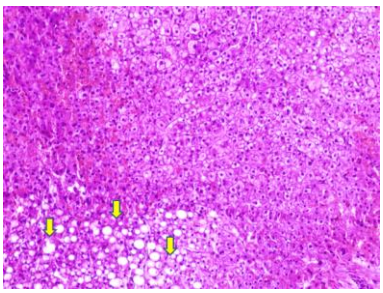
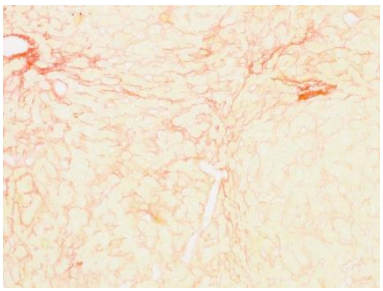
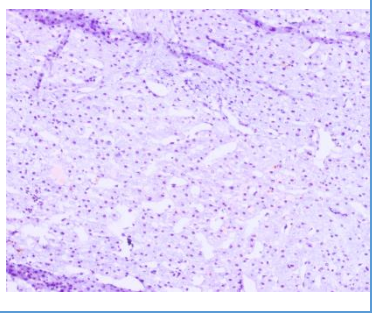
DONOR DEMOGRAPHICS

Species	Gender	Race	Age	BMI	Smoker	Alcohol Use	Drug Use
Human	Male	Caucasian	70	22.04	No	No	No

Pathology	Serological Data[1]
Colorectal Cancer	Tested negative less than 3 months before surgery

Patient informed consent was obtained. [1]The 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 limited areas with macrovesicular steatosis present (yellow arrows).

- Sirius red: Liver with incipient fibrosis, with only very discrete accumulation of Sirius red staining in portal areas. Minimal matrix deposition in the sinusoids close to periportal areas.

- Oil red: Limited areas with "fatty vacuolation" with red oil in hepatocytes showed macrovesicular steatosis and ballooning degeneration of hepatocytes throughout the whole liver.

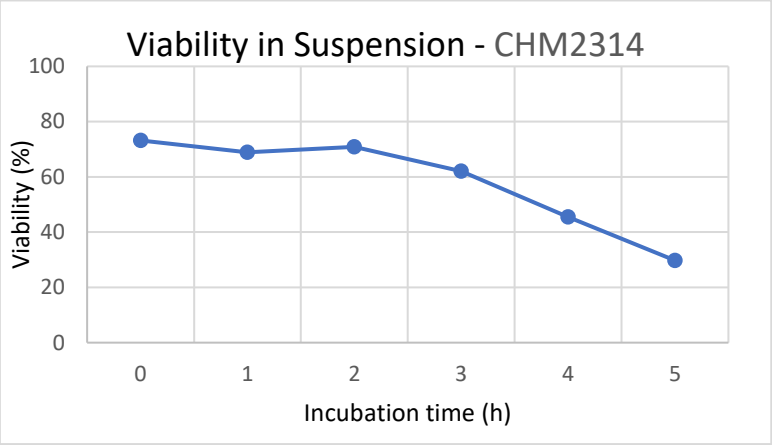
Conclusions: Liver with very light areas with matrix deposition present. Some areas of the tissue with macrovesicular steatosis and hepatocyte ballooning degeneration.

CHARACTERIZATION FOR SUSPENSION CELLS

Post Thaw Lot information	Result	SD	n
Number of viable cells (cells/vial):	$7.22x10^6$	± $0.66x10^6$	3
Post-thaw viability (%):	80.31	± 5.85	3

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 (%)	73.18	69.21	68.92	67.43	70.84	62.05	45.47	29.76
SD	± 0.00	± 1.16	± 6.98	± 3.30	± 6.32	± 1.11	± 11.67	± 5.95



Resuspended human hepatocytes suspension (0,5 * 10^6 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 SPHEROID FORMATION

Spheroid morphology
BeCytes **does not guarantee** that these primary hepatocytes will be suitable for 3D culture and creation of spheroid structures while using BeCytes protocols.

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

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	Tittle	Signature	Cytes Biotechnologies, S.L.	Date
Pilar Sainz de la Maza	Quality Manager			15/02/24

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