

## CERTIFICATE OF ANALYSIS

Lot#: HC-01

### PRODUCT DESCRIPTION

**Reference:** HuHECS/4-  
**Product:** Cryopreserved Human Hepatocytes  
**Category:** Suspension  
**Spheroid qualified:** NO  
*(see details below: 3D Spheroid formation section)*

**Isolation date:** 7<sup>th</sup> September 2017  
**Initial Isolation Viability:** 88.00%  
**Storage conditions:** -196°C using LN<sub>2</sub>  
**Sterility test:** negative for bacteria, yeast, and fungi

### DONOR DEMOGRAPHICS

Species	Gender	Race	Age	BMI	Smoker	Alcohol Use	Drug Use
Human	Male	Caucasian	65	18.04	No	No	No
Pathology		Serological Data <sup>1</sup>					
Cholangiocarcinoma		Tested negative less than 3 months before surgery					

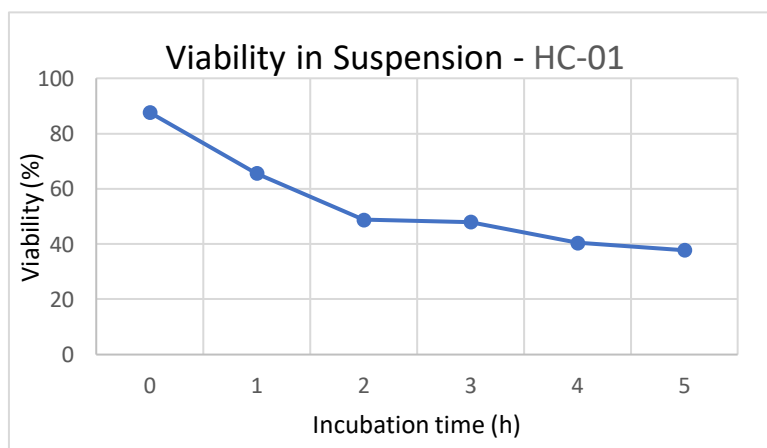
Patient informed consent was obtained. <sup>1</sup>The donor was serologically tested negative for following infectious diseases: HIV, Hepatitis B, and C. Donor medical history was also examined prior to accepting this donor. *For donor's medication information, please contact us.*

### CHARACTERIZATION FOR SUSPENSION CELLS

Post Thaw Lot information	Result	SD	n
<b>Number of viable cells/vial:</b>	2.51x10 <sup>6</sup>	± 0.04x10 <sup>6</sup>	2
<b>Viability (%):</b>	87.62	± 7.23	2

Human hepatocytes were thawed according to Cytes 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
<b>Viability (%)</b>	87.62	68.87	65.54	60.94	48.78	47.97	40.47	37.76
<b>SD</b>	± 5.12	± 2.46	± 3.64	± 1.66	± 1.22	± 4.66	± 3.39	± 0.57



Resuspended human hepatocytes suspension (0,5 \* 10<sup>6</sup> 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.

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**3D SPHEROID FORMATION**



**Spheroid morphology**

Cytes **does not guarantee** that these primary hepatocytes will be suitable for 3D culture and creation of spheroid structures.

**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	Title	Signature	Cytes Biotechnologies, S.L.	Date
Pilar Sainz de la Maza	Quality Manager			04/05/23

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**CYTES BIOTECHNOLOGIES, SL.**