

**SAMPLE**

**CERTIFICATE OF ANALYSIS**  
HUMAN CRYOPRESERVED HEPATOCYTES  
GRADE P, QUALIFIED FOR PLATEABLE ASSAYS

**Catalog number: PR-LIV-P**  
Batch number: HEP187730

FOR RESEARCH USE ONLY. Not intended for human or animal diagnostic or therapeutic uses. HUMAN CRYOPRESERVED HEPATOCYTES are not recommended for expanding. Human primary cells must be treated as potential pathogens. Users need to wear personal protective equipment during the work. DO NOT USE DRY ICE DURING WORK, STORAGE, OR TRANSPORTATION.

**1. BIOLOGICAL MATERIAL**  
**1.1. INFORMATION ABOUT DONOR**

<b>Age</b>	71 years		
<b>Sex</b>	Male <input checked="" type="radio"/> Female <input type="radio"/>		
<b>Ethnicity</b>	Caucasian <input checked="" type="radio"/> African <input type="radio"/> Not available <input type="radio"/>		
<b>Pathology or Cause of death</b>	Hemorrhagic stroke		
<b>Patient information</b>	Diabetes	Yes <input type="radio"/>	No <input checked="" type="radio"/> Unknown <input type="radio"/>
	Heart disease	Yes <input checked="" type="radio"/>	No <input type="radio"/> Unknown <input type="radio"/>
	High blood pressure	Yes <input checked="" type="radio"/>	No <input type="radio"/> Unknown <input type="radio"/>
	Smoking	Yes <input type="radio"/>	No <input checked="" type="radio"/> Unknown <input type="radio"/>
	Alcoholism	Yes <input type="radio"/>	No <input checked="" type="radio"/> Unknown <input type="radio"/>
	Medication:	-	

Biological materials were collected from the certified clinical hospitals. Clinical site provided ethical committee approval and conducted the collection in accordance to the Directive 2004/23/EC of the European Parliament

**1.2. SAFETY DATA**

<b>Virological status</b>	<b>Specification</b>	<b>Result</b>
Hepatitis B (HBs antigen, anti HBc antibody)	Negative	Positive <input type="radio"/> Negative <input checked="" type="radio"/>
Hepatitis C (anti HCV antibody)		Positive <input type="radio"/> Negative <input checked="" type="radio"/>
HIV-1 and HIV-2 (anti HIV-1 and HIV-2 antibodies)		Positive <input type="radio"/> Negative <input checked="" type="radio"/>

**1.3. LIVER TESTS**

<b>Name</b>	<b>Result</b>	<b>Reference</b>
Alanine Aminotransferase (ALT)	37	4-42 U/l
Aspartate Aminotransferase (AST)	34	4-42 U/l
Gamma-Glutamyl Transferase (GGT)	74	5-61 U/l
Creatinine	98	48-108 uM/l

Total bilirubin	15.4	5-21 uM/l
Total protein	60	57-82 g/l

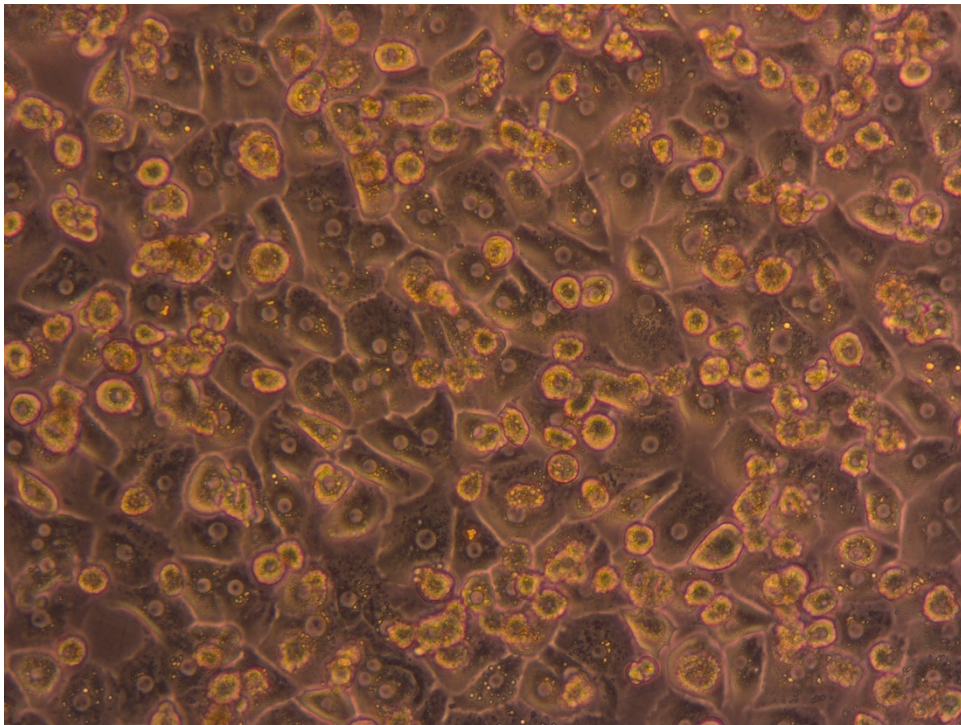
## 2. PRODUCT DESCRIPTION

Process	Human hepatocytes were isolated and frozen by standard methods.
Biosafety level	Human sourced products handled at the Biological Safety Level 2.
Date of production	15/11/2023
Cell quality control date	17/11/2023
Packaging	0.5 mL suspension in the cryovial with a minimum of 8x10 <sup>6</sup> viable cells.

## 3. CELL QUALITY CONTROL AFTER THAWING

Criteria	Specification	Result	CONCLUSION	
Post-thaw viability	≥ 80%	88 %	Yes ●	No ○
Number of viable cells per vial	≥ 8 x 10 <sup>6</sup>	9,5 x 10 <sup>6</sup>	Yes ●	No ○
Optimal Percoll concentration	25-28%	28 %	Yes ●	No ○
Cell confluence in 20-24 h of cultivation on collagen I coated plate	≥ 70%	85%	Yes ●	No ○
The ability of spheroids formation	Yes	Yes	Yes ●	No ○
Total protein test	250 µg/cm <sup>2</sup>	300 µg/cm <sup>2</sup>	Yes ●	No ○
Microbial sterility	No microbial growth detectable	Undetectable	Yes ●	No ○
Mycoplasma contamination	Standard test kit	Undetectable	Yes ●	No ○

## 4. MICROPHOTOGRAPH



24-hours of cultivation, 200x magnification

<b>Magnification</b>	x 200
<b>Cell seeding density</b>	0.5 mln cells per well
<b>Well format</b>	24-well tissue culture plate (IdMOC, Cat #71034)
<b>Cultivation conditions</b>	DMEM + 10% FBS + N21 supplement + 1% Penicillin/Streptomycin

## 5. METABOLIC ACTIVITY

Substrate	Intrinsic Clearance ( $\mu\text{L}/\text{min}/10^6$ cells)	Enzymes Responsible for Metabolism
Dextromethorphan		CYP2D6 > 3A/2C19
Diclofenac		CYP2C9, UGT2B7, UGT1A9
Verapamil		CYP3A4
4-Hydroxycoumarin		Phase II
Propranolol		CYP2D6 >1A2/2C19/UGT

Imipramine		CYP2D6/1A2/2C19/3A/ UGT1A4
Raloxifene		CYP3A
Midazolam		CYP3A4
4-methylumbelliferone		UGT1A6/9
Tolbutamide		CYP2C
Ketoprofen		UGT2B7

**6. CELL STORAGE**

<b>Delivery</b>	In liquid nitrogen, $\leq 150^{\circ}\text{C}$
<b>Storage temperature</b>	In vapour of liquid nitrogen, $\leq 150^{\circ}\text{C}$ up to 5years

**7. VISA FOR BATCH RELEASE**

<b>Name</b>	<b>Signature</b>	<b>Date</b>
Tetiana Papurina	_____	17/11/2023