

CERTIFICATE OF ANALYSIS
HUMAN CRYOPRESERVED HEPATOCYTES
GRADE **SP**, QUALIFIED FOR **SPHEROID** ASSAYS

Catalog number: PR-LIV-SPH

Batch number: HEP187725

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

Age	18 years		
Sex	Male <input checked="" type="radio"/> Female <input type="radio"/>		
Ethnicity	Caucasian <input checked="" type="radio"/> African <input type="radio"/> Not available <input type="radio"/>		
Pathology or Cause of death	Blunt head trauma		
Patient information	Diabetes	Yes <input type="radio"/>	No <input checked="" type="radio"/> Unknown <input type="radio"/>
	Heart disease	Yes <input type="radio"/>	No <input checked="" type="radio"/> Unknown <input type="radio"/>
	High blood pressure	Yes <input type="radio"/>	No <input checked="" 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

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

2. PRODUCT DESCRIPTION

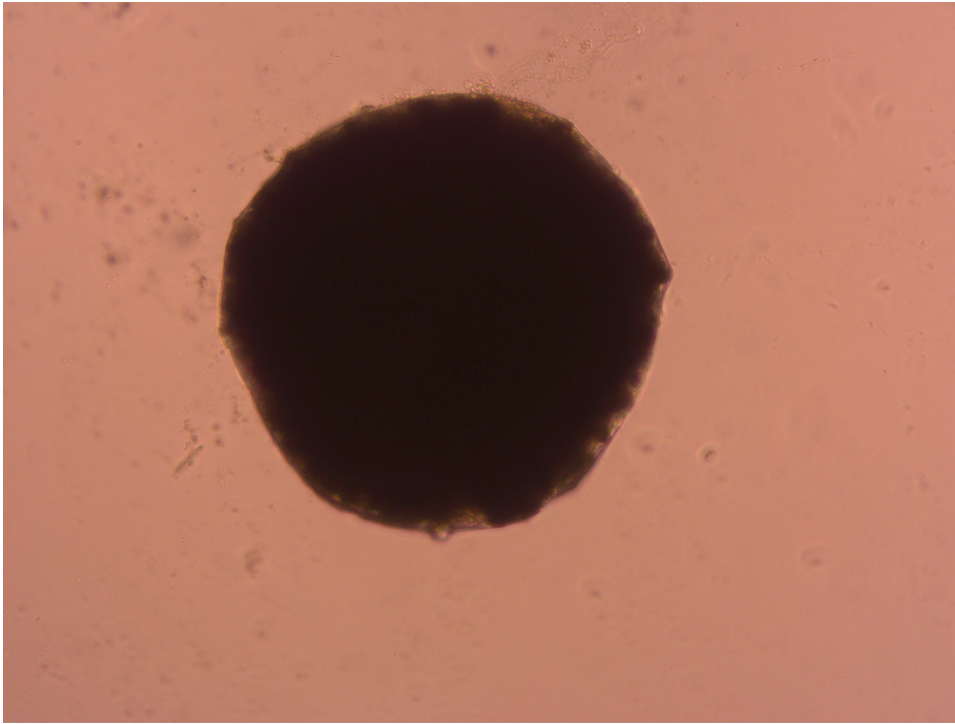
Process	Human hepatocytes were isolated and frozen by standard methods.
Biosafety level	Human sourced products handled at the Biological Safety Level 2.
Date of production	27/09/2023
Cell quality control date	29/09/2023
Packaging	0.5 mL suspension in the cryovial with a minimum of 1×10^6 viable cells.

3. CELL QUALITY CONTROL AFTER THAWING

Criteria	Specification	Result	Conclusion	
			Yes <input checked="" type="radio"/>	No <input type="radio"/>
Post-thaw viability	$\geq 80\%$	85 %	Yes <input checked="" type="radio"/>	No <input type="radio"/>
Number of viable cells per vial	$\geq 1 \times 10^6$	$1,7 \times 10^6$	Yes <input checked="" type="radio"/>	No <input type="radio"/>
The ability of spheroids formation	Yes	Yes	Yes <input checked="" type="radio"/>	No <input type="radio"/>
Number of days to form spheroids	7-14	10	Yes <input checked="" type="radio"/>	No <input type="radio"/>
Microbial sterility	No microbial growth detectable	Undetectable	Yes <input checked="" type="radio"/>	No <input type="radio"/>
Mycoplasma contamination	Standard test kit	Undetectable	Yes <input checked="" type="radio"/>	No <input type="radio"/>

4. MICROPHOTOGRAPHICS

SAMPLE




Magnification	x200
Cell seeding density	2000 cells/well
Well format	PhenoPlate™-384 ULA-coated (PerkinElmer, 6057800)
Cultivation conditions	DMEM + HepExtend supplement + 1% Penicillin/Streptomycin

5. CELL STORAGE

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

6. VISA FOR BATCH RELEASE

Name	Signature	Date
Tetiana Papurina		10/10/2023