

## Certificate of Analysis

### Human 20-Donor Pooled Cryopreserved Hepatocytes Grade S, Qualified for Suspension Assays

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

Catalog number: HEP-S-20

Batch numbers: HEP190025-TA05

#### 1. Information about donors

Batch number	Sex	Ethnicity	Age	Alcohol use	Tobacco use	Pathology or Cause of death
HEP187279	M	NA	82	No	NA	Liver metastasis
HEP187332	F	Caucasian	73	No	No	Colon cancer
HEP187369	M	Caucasian	48	Yes	NA	Liver metastasis
HEP187370	M	Caucasian	69	No	No	Cholangiocarcinoma
HEP187436	M	Caucasian	67	No	No	Colon cancer liver mets
HEP187449	F	Caucasian	64	No	No	Huge Liver
HEP187533	F	NA	53	No	NA	NA
HEP187624	F	Caucasian	45	No	No	Hepatocellular Adenoma
HEP187647	F	Caucasian	57	No	NA	CRC with Liver Metastasis
HEP187701	F	Caucasian	64	No	No	Ca recti pT3pN1pM1
HEP187711	F	Caucasian	50	No	No	Ovarian cancer liver mets
HEP187712	F	Caucasian	68	No	No	Colon cancer liver mets
HEP187714	F	Caucasian	48	No	No	Cholangiocarcinoma
HEP187716	F	Caucasian	55	No	No	Cholangiocarcinoma
HEP187719	M	Caucasian	70	No	No	Colon cancer liver mets
HEP187721	M	Caucasian	62	No	No	Colon cancer liver mets
HEP187725	M	Caucasian	18	No	No	Left hepatectomy
HEP187726	M	Caucasian	59	No	No	Hemorrhagic stroke
HEP187727	M	Caucasian	63	NA	NA	Colon cancer liver mets
HEP187730	M	Caucasian	71	No	No	Hemorrhagic stroke

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

## 2. Viral RNA Detection by qPCR

Virus	Specification	Result
Hepatitis B		Positive <input type="radio"/> Negative <b>X</b>
Hepatitis C	Negative	Positive <input type="radio"/> Negative <b>X</b>
HIV-1 and HIV-2		Positive <input type="radio"/> Negative <b>X</b>

## 3. Product Information

Process	Human hepatocytes were isolated from liver resection or autopsy by standard methods. The different batches of human hepatocytes were then pooled and frozen using a proprietary pooling process of TRL-Lonza under a license agreement
Biosafety level	Human-sourced products should be handled at the Biological Safety Level 2 (BSL 2)
Last Control Date	24/01/2024
Packaging	1 ml vial with a minimum of $5 \times 10^6$ viable cells
Quality Grade	Grade S qualified as non-plateable cryohepatocytes for suspension and metabolism assay.

## 4. Cell Quality Control after Thawing

Criteria	Specification	Result	Conclusion
Post-thaw viability	$\geq 75\%$	88 %	Yes <b>X</b> No <input type="radio"/>
Number of viable cells per vial	$\geq 5 \times 10^6$	$5.3 \times 10^6$	Yes <b>X</b> No <input type="radio"/>
Microbial sterility	No microbial growth detectable	Undetectable	Yes <b>X</b> No <input type="radio"/>

## 5. Functional Controls After Thawing

Substrate	Activity	Enzyme	Clint $\mu\text{L}/\text{min}/\text{mln cells}$
Phenacetin 1 $\mu\text{M}$	Phenacetin O-deethylation	CYP1A2	4.7
Coumarin 1 $\mu\text{M}$	Coumarin 7-hydroxylation	CYP2A6	49
Bupropion 1 $\mu\text{M}$	Bupropion hydroxylation	CYP2B6	1.8
Amodiaquine 1 $\mu\text{M}$	Amodiaquine N-deethylation	CYP2C8	642
Diclofenac 1 $\mu\text{M}$	Diclofenac 4'-hydroxylation	CYP2C9	11
Mephenytoin 5 $\mu\text{M}$	Mephenytoin hydroxylation	CYP2C19	0.08
Dextromethorphan 1 $\mu\text{M}$	Dextromethorphan O-demethylation	CYP2D6	11
Chlorzoxazone 1 $\mu\text{M}$	Chlorzoxazone 6-hydroxylation	CYP2E1	0
Testosterone 5 $\mu\text{M}$	Testosterone 6 $\beta$ -hydroxylation	CYP3A4/5	0.7
Nifedipine 1 $\mu\text{M}$	Nifedipine oxidation	CYP3A4/5	12

## 6. 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

## 7. Visa for Batch Release

Name	Signature	Date
Tetiana Papurina		13/02/2024