Certificate of Analysis

Human 10-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-10

Batch numbers: HEP190027

1. Information about donors

Batch number	Sex	Ethnicity	Age	Alcohol use	Tobacco use	Pathology or Cause of death
HEP723	F	Caucasian	64	No	No	Hepatocellular carcinoma
HEP725	M	Caucasian	18	No	No	Blunt head trauma
HEP730	M	Caucasian	71	No	No	Hemorrhagic stroke
HEP732	F	Caucasian	38	No	No	Right Hemangioma
HEP736	F	Caucasian	71	No	No	Hemorrhagic stroke
HEP737	M	Caucasian	74	No	No	Rectal cancer
HEP743	M	Caucasian	71	No	No	Sigmoid colon cancer
HEP745	F	Caucasian	63	No	No	Cancer colon
HEP747	M	Caucasian	61	No	No	Colon cancer
HEP748	F	Caucasian	86	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	Negative	Positive ◯	Negative **X**
Hepatitis C		Positive ◯	Negative **X**
HIV-1 and HIV-2		Positive ◯	Negative **X**

3. Product Information

Process	Human hepatocytes were isolated from liver resection and liver 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	10/09/2024
Packaging	1 ml vial with a minimum of 5 x 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	≥ 75 %	92 %	Yes **X**	No ◯
Number of viable cells per vial	≥ 5 x 10^6	6.7 x 10^6	Yes **X**	No ◯
Microbial sterility	No microbial growth detectable	Undetectable	Yes **X**	No ◯

5. Functional Controls After Thawing

Substrate	Activity	Enzyme	Clint µL/min/mln cells
Phenacetin 1 µM	Phenacetin O-deethylation	CYP1A2	**2.9**
Coumarin 1 µM	Coumarin 7-hydroxylation	CYP2A6	**18.6**
Bupropion 1 µM	Bupropion hydroxylation	CYP2B6	**1.9**
Amodiaquine 1 µM	Amodiaquine N-deethylation	CYP2C8	**TBD**
Diclofenac 1 µM	Diclofenac 4'-hydroxylation	CYP2C9	**23.6**
Mephenytoin 5 µM	Mephenytoin hydroxylation	CYP2C19	**0.019**
Dextromethorphan 1 µM	Dextromethorphan O-demethylation	CYP2D6	**14.5**
Chlorzoxazone 1 µM	Chlorzoxazone 6-hydroxylation	CYP2E1	**0.96**
Testosterone 5 µM	Testosterone 6β-hydroxylation	CYP3A4/5	**0.232**
Nifedipine 1 µM	Nifedipine oxidation	CYP3A4/5	**11.5**

6. Cell Storage

Delivery	In liquid nitrogen, ≤ -150^{o}C
Storage temperature	In vapour of liquid nitrogen, ≤ -150^{o}C up to 5 years

7. Visa for Batch Release

Name	Signature	Date
Tetiana Papurina		16/09/2024