CERTIFICATE OF ANALYSIS

HUMAN CRYOPRESERVED HEPATOCYTES
plateable, for in vitro analysis
Catalog number: HH1

PLATEABLE	Batch number: HH1-23011

FOR RESEARCH USE ONLY. CAUTION: Not intended for human or animal diagnostic or therapeutic uses. Users should treat all human and animal cells as potential pathogens. Wear protective clothing and eyewear. Practice appropriate disposal techniques for potentially pathogenic or bio-hazardous materials.

Biological Material

Subject	Human
Age	68
Sex	Female
Ethnicity	Caucasian
Pathology	Colorectal Cancer, liver metastasis
Diabetes	No
Heart disease	No
High blood pressure	No
Smoking	No
Alcoholism	No
Medication	Chemotherapy 2nd line
Virological status	Negative for HBV, HCV, HIV

Product

Process	Hepatocytes were isolated and frozen by standard methods
Cell quality control date	26/07/2023
Packaging	0.5 mL vial with a minimum of 5 x 10^6 viable cells

Cell Quality Control

Criteria	**Specification with one-step thawing protocol**	**Result**	PASS/FAIL
Post-thaw viability	≥ 80 %	-83%	PASS
Number of viable cells per vial	≥ 5 x 10^6	(7 x 10^6)	PASS
Plateability (post-attachment, in seeding medium)	Ability to attach to collagen coated plate after overnight plating	Yes	PASS
Microbial sterility (under standard use conditions)	No microbial growth detectable	(Undetectable)	PASS

Metabolic characterization

Substrate	Intrinsic Clearance (µL/min/10^6 cells)	Enzymes Responsible for Metabolism
Dextromethorphan	7,2	CYP2D6 > 3A/2C19
Diclofenac	48,8	CYP2C9, UGT2B7, UGT1A9
Verapamil	27,8	CYP3A4
4-Hydroxycoumarin	104,5	Phase II
Propranolol	10,9	CYP2D6 >1A2/2C19/UGT
Imipramine	8,7	CYP2D6/1A2/2C19/3A/ UGT1A4
Raloxifene	38,5	CYP3A
Midazolam	16,4	CYP3A4
4-methylumbelliferone	70,3	UGT1A6/9
Tolbutamide	3,1	CYP2C
Ketoprofen	13,8	UGT2B7

Cell Storage

Delivery and storage	Liquid nitrogen

Product Certification

Name	Signature	Date
Tetiana Papurina		10.07.2023