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

BIOIOgical 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	СҮРЗА	
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
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Product Certification

Name	Signature	Date
Tetiana Papurina	time	10.07.2023

Material is intended for the research purpose only, not for diagnostic or therapeutic use. Biological materials were collected from the certified clinical hospitals from the liver tumor resection. Clinical site provided ethical committee approval and conducted the collection in accordance to the Directive 2004/23/EC of the European Parlament, and following the regulations of the local Ministry of Health

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