

SAMPLE**CERTIFICATE OF ANALYSIS**

10-Donor POOL CRYOPRESERVED SUSPENSION
HEPATOCYTES

Suspension, for in vitro analysis

Catalog number: HH2

SUSPENSION

Batch number: HH2-23008

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.

1. Biological Material

Lot number	Gender	Ethnicity	Age	BMI	Tobacco use	Alcohol use	(HIV/ HBV/ HCV)	Pathology
LIN09-102	F	Caucasian	64	NA	No	No	Negative	Huge liver NET
LIN09-103	F	Caucasian	64	NA	No	No	Negative	Ca recti pT3pN1pM1 (hep, pulmon)
LIN02-101	M	Caucasian	60	NA	No	No	Negative	Ca colon pT4N1M1(hep), IV stage
LIN09-106	F	Caucasian	50	NA	No	No	Negative	Perihilar cholangiocarcinoma, cT3N1M0
LIN02-104	F	Caucasian	50	NA	No	No	Negative	Peripheral perihilar cholangiocarcinoma
LIN09-110	M	Caucasian	70	NA	No	No	Negative	(Klatskin tumor) cT1bN0M0
LIN02-105	M	Caucasian	63	NA	No	No	Negative	Liver cyst
LIN02-106	F	Caucasian	50	NA	No	No	Negative	Ovarian cancer T1N0M0 2021. Disease progression. Liver Mts
LIN02-110	M	Caucasian	59	NA	NA	Yes	Negative	Bile duct cancer (cholangiocarcinomas)
LIN02-114	M	Caucasian	57	NA	Yes	No	Negative	Hydatid cyst of the liver

2. Product

Process	Hepatocytes were isolated and frozen by standard methods
Cell quality control date	July 26th 2023
Packaging	1.0 mL vial with a minimum of 5×10^6 viable cells

3. Cell Quality Control

Criteria	Specification with one-step thawing protocol	Result	PASS/FAIL
Post-thaw viability	$\geq 80 \%$	-85%	PASS
No. viable cells per vial	$\geq 5 \times 10^6$	(6.85×10^6)	PASS
Plateability (post-attach, 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

4. Functional controls after thawing

Controls performed on suspended cells

Client value of the probe substrates for the Phase I enzymes ($\mu\text{L}\cdot\text{min}^{-1}\cdot\text{million cells}^{-1}$)

Substrate	Main enzyme involved	Result	Historic data					
			Min	1st quartile	Med	3rd quartile	Max	n
Phenacetin	CYP1A2	2.3	0.8	1.6	2.3	2.6	2.9	3
Coumarin	CYP2A6	24	15	20	24	33	41	3
Bupropion	CYP2B6	0.5	0.4	0.5	0.5	0.7	0.8	3
Amodiaquine	CYP2C8	98	36	63	89	94	98	3
Diclofenac	CYP2C9	9.2	6.7	8	9.2	10	11	3
Mephénytoin	CYP2C19	0.07	0.01	0.04	0.06	0.07	0.07	3
Dextromethorphan	CYP2D6	7.6	4.5	5.6	6.6	7.1	7.6	3
Chlorzoxazone	CYP2E1	NA*						3
Testosteron	CYP3A4/ 5	1.1	0.2	0.5	0.7	0.9	1.1	3
Nifedipine	CYP3A4/ 5	2.6	2.6	3.2	3.7	7.4	11	3

5. Cell Storage

Delivery and storage	Liquid nitrogen
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6. Product Certification

Name	Signature	Date
Andrey Simonov		July 13, 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 Parliament, and following the regulations of the local Ministry of Health

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