

# **CERTIFICATE OF ANALYSIS** CRYOPLATEABLE HUMAN HEPATOCYTES

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

### **PRODUCT INFORMATION:**

Product name:	Lot identifier:			
Post-thaw viability of $\geq $ %	Post-thaw confluency $\geq$ % on day 5			
Contains a minimum of x 10 <sup>6</sup> viable cells/mL				
DONOR DEMOGRAPHICS:				
Sex: Age: BMI: Ethnicity:	COD:			
Donor negative for: HIV, HCV, HBV, RPR	Culture negative for: Gram+, Gram-, Mycoplasm, Fungi			
PLATING:				
Recommended seeding density (million cells/mL):	Recommended thaw medium:			
Lot hours post-plating	Lot hours post-plating			
ΜΕΤΔΒΟΙ Ις Αςτινιτγ				

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ENZYME	SUBSTRATE	CONCENTRATION (µM)	ENZYME ACTIVITY (pmole/min/million cells)
CYP1A2	Phenacetin	100	
CYP3A4	Testosterone	100	
CYP2B6	Bupropion	500	

Hepatocytes in suspension (0.5 million/mL) were incubated with substrate at 37°C in 5% CO<sub>2</sub> and 90% humidity for 30 minutes, respectively. The concentrations of the metabolites were determined using LC-MS/MS methods.

### TRANSPORTER ACTIVITY

TRANSPORTER	SUBSTRATE	UPTAKE ACTIVITY RATE (pmole/min/million cells)
OATP1B1/3	Estrone 3-sulfate	
OATP1B1/3	Rosuvastatin	
OCT1/2	1-Methyl-4-phenylpyridinium iodide	
NCTP	Taurocholic acid	

Hepatocytes in suspension (0.5 million/mL) were incubated in substrate (10  $\mu$ M) on ice and then at 37°C for 3 minutes, respectively. Hepatocytes were separated from the medium by oil-spin method. The substrate concentrations were determined by specific LC/MSMS method.

TRANSPORTER	SUBSTRATE	EXPORT ACTIVITY RATE (pmole/min/million cells)
BSEP	Glycocholic acid	

Hepatocytes in suspension (0.25 million/mL) were incubated with cholic acid-d4 (10  $\mu$ M) at 37°C in 5% CO<sub>2</sub> and 90% humidity for 60 minutes. The concentration of glycocholic acid were determined using a LC/MSMS method.

The cells from this lot were derived from tissue obtained from accredited institutions. Consent was obtained by these institutions from the donor or the donor's legal next of kin, for use of the tissue and its derivatives for research purposes.

Najah Abi-Gerges, PhD. VP, Research & Development

Date



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## **RESEARCH ONLY**

# **Donor Demographic Form**

### **Donor Information**

Age:	68	Ethnicity:	Caucasian	Sex:	Female
Height (cm):		Weight (kg):	58.5	BMI:	21.5
COD:	Anoxia/Natural Causes				

Consent for Research confirmed through visual by AnaBios Coordinator (Yes or No): Yes

#### Past Medical History

D : , D:	–	<b>N N</b>	
Respiratory Disease	No 🗆	Yes 🖂	Asthma, occasional mild symptoms in the last 10-15 years d/t allergies
Cardiac Disease	No 🗆	Yes 🗵	Pacemaker, unk details
Hypertension	No 🖾	Yes 🗆	
Neurological Disease	No 🖂	Yes 🗆	
Cancer	No 🗆	Yes 🖂	Basal cell, squamous cell skin cancer on hand 3 years ago, surgically removed and considered cured, all follow ups have remained clear
Diabetes	No 🖂	Yes 🗆	
Liver Disease	No 🖾	Yes 🗆	
GI Disease	No 🗆	Yes 🖂	IBS, on and off diarrhea all the time d/t enzyme deficiency GSID
Kidney Disease	No 🖂	Yes 🗆	
Urinary Tract Disease	No 🖾	Yes 🗆	
Tobacco	No 🖂	Yes 🗆	
Alcohol	No 🖂	Yes 🗆	
Drug Use	No 🖂	Yes 🗆	
Medication Home	No 🗆	Yes 🛛	Unk prescriptions for GSID. Noted "extensive medication list". Afrin nasal spray as needed, multivitamins.

Comments

Severe chin-on-chest deformity (now s/p C3-C7 ACDF with C2-L1 PFF on 12/28 and 12/30). GSID. Fall resulting in neck fractures in August 2022.

#### Serology

	(Yes/No)	<u>Negative</u>	<b>Positive</b>		(Yes/No)	<b>Negative</b>	<b>Positive</b>
Anti – HCV	Yes	Negative	-	HBs Ab	No	-	-
Anti – HIV 1/2	Yes	Negative	-	HBs Ag	Yes	Negative	-
Anti – HTLV 1/2	No	-	-	RPR/STS/VDRL	Yes	Negative	-
CMV	Yes	Negative	-	HCV NAT	Yes	Negative	-
CMV IgG	No	-	-	HCV RIBA	No	-	-
CMV IgM	No	-	-	HIV NAT	Yes	Negative	-
EBNA	No	-	-	WNV IgM	No	-	-
EBV IgG	No	-	-	HBV	Yes	Negative	-
EBV IgM	No	-	-	Тохо	No	-	-
HBc Total	Yes	Negative	-	WNV NAT	Yes	Negative	-
HBc Ab IgG	No	-	-	Chagas	Yes	Negative	-
HBc Ab IgM	No	-	-	SARS-CoV-2	Yes	Negative	-

#### Authorized by:

Any Cay

23 Mar 2023 Date

Signature