

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:

CYP1A2

CYP2A6

CYP2B6

CYP2C8

Product name:	Lot identifier:
Post-thaw viability of ≥%	Post-thaw confluency ≥% on day 5
Contains a minimum of x 10 ⁶ viable cells/mL	
DONOR DEMOGRAPHICS:	
Sex: Age: BMI: Eth	nicity: 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-plat	* Carboxy-DCFDA was used to visualize the bile canaliculi
METABOLIC ACTIVITY	formation in polarized hepatocytes.
ENZYME SUBSTRAT	TE CONCENTRATION (μM) ENZYME ACTIVITY (pmole/min/million cells)

100

50

500

20

Phenacetin

Coumarin

Bupropion

Amodiaquine

METABOLIC ACTIVITY (cont.)

ENZYME	SUBSTRATE	CONCENTRATION (µM)	ENZYME ACTIVITY (pmole/min/million cells)	
CYP2C9	Diclofenac	25		
CYP2C19	S-mephenytoin	250		
CYP2D6	Dextromethorphan	15		
CYP2E1	Chlorzoxazone	250		
CYP3A4	Testosterone	100		
CYP3A4	Midazolam	20		
Phase I CYP	7-ethoxycoumarin	100		
SULT	SULT 7-hydroxycoumarin sulfation			
UGT	7-hydroxycoumarin glucuronidation	100		
AO	AO Zoniporide			

Hepatocytes in suspension (0.5 million/mL) were incubated with substrate at 37° C in 5% CO₂ 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	
OCT1/2	1-Methyl-4-phenylpyridinium iodide	
NCTP	Taurocholic acid	

Hepatocytes in suspension (0.5 million/mL) were incubated in substrate (10 μ 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 μ M) at 37°C in 5% CO₂ 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



3030 Bunker Hill Street, Suite 312 San Diego, CA 92109 <u>www.anabios.com</u> For inquiries, please contact us at <u>info@anabios.com</u>.



3030 Bunker Hill, Suite 312 San Diego, CA 92109 Tel: 858-224-7361 Fax: 858-224-7371 www.anabios.com

RESEARCH ONLY

Donor Demographic Form

Donor Information

Age:	48	Ethnicity:	Caucasian	Sex:	М
Height (cm):	175.3	Weight (kg):	78.2	BMI:	25.5
COD:	Anoxia/Drug Intoxication				

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

Past Medical History

Respiratory Disease	No 🖂	Yes 🗆	
Cardiac Disease	No 🖂	Yes 🗆	
Hypertension	No 🗆	Yes 🛛	3 weeks ago
Neurological Disease	No 🖂	Yes 🗆	
Cancer	No 🖂	Yes 🗆	
Diabetes	No 🖾	Yes 🗆	
Liver Disease	No 🖾	Yes 🗆	
GI Disease	No 🖂	Yes 🗆	
Kidney Disease	No 🖾	Yes 🗆	
Urinary Tract Disease	No 🖾	Yes 🗆	
Tobacco	No 🖂	Yes 🗆	
Alcohol	No 🗆	Yes 🗵	12-15 beers or liquor drinks daily for 30 years
Drug Use	No 🗆	Yes 🗵	Snorted Amphetamines on and off, maybe 5-6 times a month for more than 5 years
Medication Home	No 🗆	Yes 🖂	Lisinopril, Librium, Trazodone, Ibuprofen, Potassium, Men's daily multivitamin

Comments

None

Serology

	(Yes/No)	<u>Negative</u>	Positive		(Yes/No)	<u>Negative</u>	Positive
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	No	-	-	HCV NAT	Yes	Negative	-
CMV IgG	Yes	-	Positive	HCV RIBA	No	-	-
CMV IgM	No	-	-	HIV NAT	Yes	Negative	-
EBNA	No	-	-	WNV IgM	No	-	-
EBV IgG	No	-	-	HBV	Yes	Negative	-
EBV IgM	No	-	-	Toxo	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:

Ing Cay Signature

18-Jan-2023

Date