

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

CYP2B6

CYP2C8

Product name:		Lot identifier:			
Post-thaw viability of $\geq \$ %		Post-thaw confluency ≥% on day 5			
Contains a minimum of x 10 ⁶	viable cells/mL				
DONOR DEMOGRAPHIC	S:				
Sex: Age:	BMI: Ethnicity:	COD:			
Donor negative for: HIV, HCV, HB	/, RPR	Culture negative for: Gram+, Gra	am-, Mycoplasm, Fungi		
PLATING:					
Recommended seeding density (r	nillion cells/mL):	Recommended thaw medium: _			
Lot	hours post-plating	Lot			
METABOLIC ACTIVITY		*Carboxy-DCFDA was used to visualize the bile canaliculi formation in polarized hepatocytes			
ENZYME	SUBSTRATE	CONCENTRATION (µM)	ENZYME ACTIVITY (pmole/min/million cells)		

100

500

20

Phenacetin

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		
CYP3A4	Testosterone	100		
CYP3A4	Midazolam	20		
Phase I CYP	7-ethoxycoumarin	100		
SULT	7-hydroxycoumarin sulfation	100		
UGT	7-hydroxycoumarin glucuronidation	100		
AO	Zoniporide	100		

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.

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:	30	Ethnicity:	Hispanic	Sex:	Male
Height (cm):	175	Weight (kg):	79.3	BMI:	25.9
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 🗆	
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 🖂	1 pint of hard liquor on and off for 4-5x/week, sometimes daily, for 5 years
Drug Use	No 🗆	Yes 🛛	Smoked or orally ingested Heroin, Marijuana, Fentanyl, and Percocet – used on and off for 1-2 years, last used 9/20/22, unk amount. Found with drug paraphernalia, tox screen positive for THC upon admission.
Medication Home	No 🗆	Yes 🖂	Cod Liver oil vitamin daily
Comments	Tremors	s in July o	r Aug 2022 d/t alcohol withdrawals

Serology

	(Yes/No)	Negative	Positive		(Yes/No)	Negative	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	Yes	-	Positive	HBV	Yes	Negative	-
EBV IgM	No	-	-	Toxo	Yes	Negative	-
HBc Total	No	-	-	WNV NAT	Yes	Negative	-
HBc Ab IgG	Yes	Negative	-	Chagas	Yes	Negative	-
HBc Ab IgM	No	-	-	SARS-CoV-2	Yes	Negative	-

Authorized by:

dry Cay Signature

10-10-2022

Date