

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	i:			
Product name:		Lot identifier:		
Post-thaw viability of ≥%		Post-thaw confluency ≥% on day 5		
Contains a minimum of x 10 ⁶ vi	able cells/mL			
DONOR DEMOGRAPHICS	:			
Sex: Age: Bl	MI: Ethnicity:	COD:		
Donor negative for: HIV, HCV, HBV, F	RPR	Culture negative for: Gram+, Gran	n-, Mycoplasm, Fungi	
PLATING:				
Recommended seeding density (million cells/mL):		Recommended thaw medium:		
Lot	hours post-plating	Lot	hours post-plating	

METABOLIC ACTIVITY

ENZYME	SUBSTRATE	CONCENTRATION (μM)	ENZYME ACTIVITY (pmole/min/million cells)
CYP1A2	Phenacetin	100	
CYP2B6	Bupropion	500	
CYP2C8	Amodiaquine	20	

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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AnaBios Lot Number: 1141

RESEARCH ONLY

Donor Demographic Form

Donor	In	form	ation
Dunui	III	j VI III	uuvn

Age:11 monthsEthnicity:CaucasianSex:MaleHeight (cm):76.2Weight (kg):10.5BMI:18.1

COD: Anoxia/Drowning

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

Past Medical History

Respiratory Disease	No 🗵	Yes \square
Cardiac Disease	No 🗵	Yes □
Hypertension	No 🗵	Yes \square
Neurological Disease	No 🗵	Yes \square
Cancer	No 🗵	Yes □
Diabetes	No 🗵	Yes □
Liver Disease	No 🗵	Yes \square
GI Disease	No 🗵	Yes □
Kidney Disease	No 🗵	Yes \square
Urinary Tract Disease	No 🗵	Yes □
Tobacco	No 🗵	Yes □
Alcohol	No 🗵	Yes □
Drug Use	No 🗵	Yes \square
Medication Home	No 🗵	Yes \square

Comments N/A

Serology

	(Yes/No)	<u>Negative</u>	<u>Positive</u>		(Yes/No)	<u>Negative</u>	<u>Positive</u>
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	Negative	-	HCV RIBA	No	-	-
CMV IgM	No	-	-	HIV NAT	Yes	Negative	-
EBNA	No	-	-	WNV IgM	No	-	-
EBV IgG	Yes	Negative	-	HBV	Yes	Negative	-
EBV IgM	No	-	-	Toxo	Yes	Negative	-
HBc Total	Yes	Negative	-	WNV NAT	No	-	-
HBc Ab IgG	No	-	-	Chagas	No	-	-
HBc Ab IgM	No	-	-	SARS-CoV-2	Yes	Negative	-

Authorized by:

6-23-2022

Signature