

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.

ION:				
	Lot identifier:			
	Post-thaw confluency ≥% on day 5			
10 ⁶ viable cells/mL				
IICS:				
BMI: Ethnicity:	COD:			
HBV, RPR	Culture negative for: Gram+, Gram-, Myco	olasm, Fungi		
y (million cells/mL):	Recommended thaw medium:			
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hours post-plating	Lot hours	s post-plating		
	10° viable cells/mL IICS: BMI: Ethnicity: HBV, RPR y (million cells/mL):	Lot identifier: Post-thaw confluency ≥% on day 5 10° viable cells/mL IICS: BMI: Ethnicity: COD: HBV, RPR Culture negative for: Gram+, Gram-, Mycol y (million cells/mL): Recommended thaw medium:		

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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Organ: Liver **AnaBios Lot Number: 658**

Sex:

RESEARCH ONLY

Female

Donor Demographic Form

Caucasian

Ethnicity:

Donor 1	Inform	ation
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Age:

Height (cm):	156				Weight (kg):	62.3	BMI:	25.5	
COD:	Anox	ia/Drug Into	xication						
Consent for Research	n confirm	ed through vi	sual by Ar	naBios Coor	dinator (Yes or N	No): Yes			
Past Medical H	listory								
Respiratory Dis	sease	No 🗵	Yes □						
Cardiac Diseas	e	No 🗵	Yes □						
Hypertension		No 🗵	Yes □						
Neurological D	Disease	No 🗆	Yes ⊠			onths in 2022 after pregoeing confused and forg			mental ability in
Cancer		No 🗵	Yes □		F	8	9 · · · · · · · · · · · · · · · · · · ·		
Diabetes		No 🗵	Yes □						
Liver Disease		No 🗵	Yes □						
GI Disease		No 🗵	Yes □						
Kidney Disease	e	No 🗵	Yes □						
Urinary Tract I		No 🗵	Yes □						
Tobacco		No ⊠	Yes □						
Alcohol		No ⊠	Yes □						
Drug Use Medication Ho	ome	No □	Yes ⊠ Yes ⊠	Injected pills and d/t overd	Heroin 1x/mon Xanax in purse lose.	oriety program. Meth, C on tha year ago – not use e, tox screen positive to nsomnia; Tylenol for s	d w/in last 6 mc Benzos upon a	onths. Found with dmission. Visited	unknown blue
Comments		Insomnia	ı.						
Serology									
		(Yes/No)	<u>Ne</u>	<u>gative</u>	Positive		(Yes/No)	Negative	Positive
Anti – HCV		Yes	Ne	egative	-	HBs Ab	No	-	-
Anti – HIV 1/2		Yes	Ne	egative	-	HBs Ag	Yes	Negative	-
Anti – HTLV 1	1/2	No		-	-	RPR/STS/VDRL	Yes	Negative	-
CMV		No		-	-	HCV NAT	Yes	Negative	-
CMV IgG		Yes			Positive	HCV RIBA	No	-	-
CMV IgM		Yes	Ne	egative	-	HIV NAT	Yes	Negative	-
EBNA		No		-	- D'4'	WNV IgM	Yes	Negative	-
EBV IgG		Yes	Na.T.	-	Positive	HBV	Yes	Negative	-
EBV IgM		Yes		egative	-	Toxo	Yes	Negative	-
HBc Total		Yes	INC	egative	-	WNV NAT	Yes	Negative	-
HBc Ab IgG		No		-	-	Chagas	Yes	Negative	-
HBc Ab IgM		No		-	-	SARS-CoV-2	Yes	Negative	-

Authorized by:

7-7-2022

Signature