

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 10⁶ viable cells/mL

DONOR DEMOGRAPHICS:

Sex: _____ Age: _____ BMI: _____ Ethnicity: _____ COD: _____

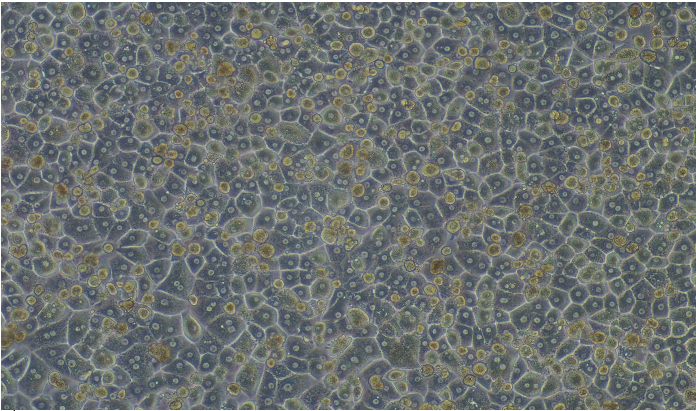
Donor negative for: HIV, HCV, HBV, RPR

Culture negative for: Gram+, Gram-, Mycoplasm, Fungi

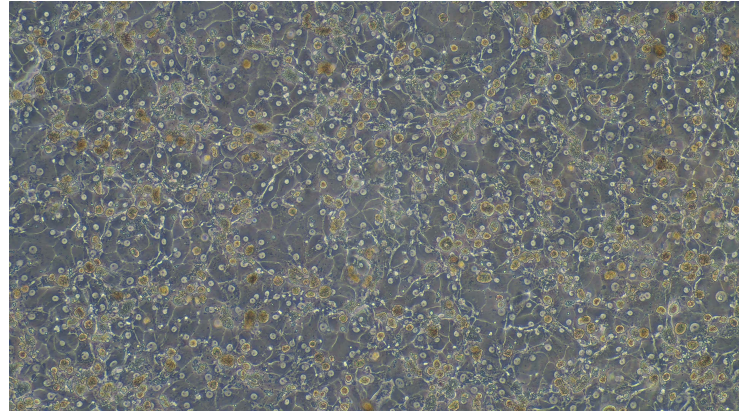
PLATING:

Recommended seeding density (million cells/mL): _____

Recommended thaw medium: _____



Lot _____ hours post-plating



Lot _____ hours post-plating*

METABOLIC ACTIVITY

ENZYME	SUBSTRATE	CONCENTRATION (μ M)	ENZYME ACTIVITY (<i>pmole/min/million cells</i>)
CYP1A2	Phenacetin	100	
CYP2B6	Bupropion	500	
CYP2C8	Amodiaquine	20	

METABOLIC ACTIVITY *(cont.)*

ENZYME	SUBSTRATE	CONCENTRATION (μM)	ENZYME ACTIVITY (<i>pmole/min/million cells</i>)
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.

ENZYME INDUCTION ACTIVITY

ENZYME	TREATMENT	mRNA FOLD-CHANGE
CYP1A2	Omeprazole (25 μM)	
CYP2B6	Phenobarbital (2 mM)	
CYP3A4	Rifampin (10 μM)	

Hepatocytes were seeded on a 24-well plate pre-coated with collagen I, and cultured for 48 hours at 37°C in 5% CO₂ and 90% humidity. The hepatocytes were then incubated at 37°C in 5% CO₂ and 90% humidity with omeprazole (25 μM , CYP1A2), phenobarbital (2 mM, CYP2B6), rifampin (10 μM , CYP3A4) and vehicle control for 48 hours, respectively. The media were replaced every 24 hours with fresh media containing the positive inducers and vehicle. The mRNA levels of CYP1A2, CYP2B6 and CYP3A4 were determined using RT-PCR.

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
VP, Research & Development

Date

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Donor Demographic Form

Donor Information

Age: 57 Ethnicity: Caucasian Sex: Female
 Height (cm): 157 Weight (kg): 52.5 BMI: 21.3
 COD: Anoxia/Cardiovascular

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

Past Medical History


Respiratory Disease	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	As a child
Cardiac Disease	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Hypertension	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	For 1 year – resolved through diet
Neurological Disease	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	Frequent migraines
Cancer	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Diabetes	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Liver Disease	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
GI Disease	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Kidney Disease	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Urinary Tract Disease	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Tobacco	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Alcohol	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	Drank one margarita occasionally x 35 years, one beer weekly x 35 years
Drug Use	No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	
Medication Home	No <input type="checkbox"/>	Yes <input checked="" type="checkbox"/>	Zomig, Flonase, Zyrtec, Turmeric, Collagen, Probiotic, Vitamin C, Zinc, Magnesium, Disophrol, Calcium Carbonate, Vitamin D3

Comments Arthritis in hands; Tox screen positive for Fentanyl upon admission. Spinal surgery T4, T5 fused in 2017

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

Authorized by:



 Signature

08-03-2022

 Date