

Male Human Hepatocytes – Individual, Cryoplateable

Product: M00995-P | Lot: RAS *****

Storage: ≤ -150 °C

Post-Thaw Viability and Yield

	<u>Specification</u>	<u>Results</u>
Viability	≥ 70% post-thaw viability by trypan blue exclusion	91 %
Yield	≥ 5 million viable cells <i>Post-thaw viability and yield are an average of samples from the beginning, middle, and end of the production run.</i>	7.81 million viable cells

***** Preliminary COA – To be updated when mRNA is available.

Enzyme Induction

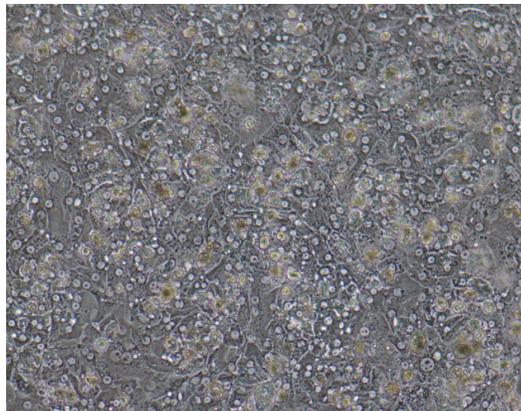
Enzyme	Inducer	Substrate	Metabolite	Basal Rate*	PC/VC Ratio*	mRNA Fold Induction*
CYP1A2	50 µM Omeprazole	100 µM Phenacetin	Acetaminophen	11.7	12.7	TBD
CYP2B6	1 mM Phenobarbital	150 µM Bupropion	Hydroxybupropion	9.04	4.56	TBD
CYP3A4	25 µM Rifampin	125 µM Testosterone	6β-Hydroxytestosterone	24.0	6.83	TBD

*Basal rate of metabolite formation is measured on day 5. PC/VC induction ratio & mRNA are measured after 48 hours of exposure to inducers. mRNA measured by qRT-PCR analysis (TaqMan™). Metabolite rate of formation is measured in pmol/min/10⁶ cells after a 4 hours cell incubation at 37°C, 5% CO₂. Assays are run in triplicate and analyzed by LC/MS/MS validated procedures.

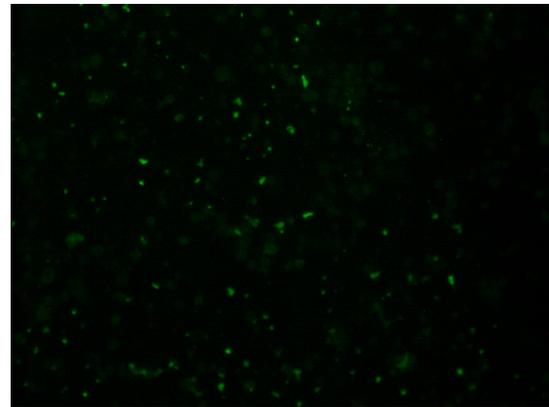
MTT Viability & Confluence

	<u>Specification</u>	<u>Results</u>
MTT	≥ 0.1 OD MTT value at day 5	0.349 OD
Confluence	≥70% confluent monolayer at day 5 (no overlay)	98 %

Phase contrast image of plated cells (Day 5)



CDFDA staining (Day 5)



Cryopreserved hepatocytes were thawed and suspended in BioIVT INVITROGRO™ CP medium at a seeding density of 0.7 million viable cells/mL onto BioCoat® 24-well cell culture plates. Cultured hepatocytes were maintained in CP medium for 48-72 hours prior to introduction of inducers.

Caution: This product was prepared from human tissue. Treat all products containing human-derived materials as potentially infectious, as no known test methods can offer assurance that products derived from human tissues will not transmit infectious agents.

This product is being sold for research and/or manufacturing purposes only. The biological samples supplied by BioIVT, or any material isolated from the samples, are for in-vitro research use only and are not to be used as a source of material for clinical therapies. Human material may be used in vivo in animals. The user assumes all responsibility for its usage and disposal, in accordance with all regulations.

Metabolic Activity

Enzyme & Function	Substrate	Conc. [μM]	Metabolite	Result***
ECOD 7-Ethoxycoumarin O-Deethylation	7-Ethoxycoumarin	75	7-HC, 7-HCG, and 7-HCS**	88.7
UGT 7-Hydroxycoumarin Glucuronidation	7-Hydroxycoumarin	30	7-HCG	484
ST 7-Hydroxycoumarin Sulfation	7-Hydroxycoumarin	30	7-HCS	41.4
CYP1A2 Phenacetin O-Deethylation	Phenacetin	15	Acetaminophen	27.9
CYP2A6 Coumarin 7-Hydroxylation	Coumarin	8	7-HC, 7-HCG, and 7-HCS	90.6
CYP2B6 Bupropion Hydroxylation	Bupropion	250	Hydroxybupropion	77.7
CYP2C8 Amodiaquine N-Desethylation	Amodiaquine	20	Desethylamodiaquine	203
CYP2C9 Tolbutamide Methyl-Hydroxylation	Tolbutamide	150	4'-Methylhydroxytolbutamide	39.3
CYP2C19 S-Mephenytoin 4'-Hydroxylation	S-mephenytoin	20	4'-Hydroxymephenytoin	10.5
CYP2D6 Dextromethorphan O-Demethylation	Dextromethorphan	8	Dextrorphan	47.4
CYP2E1 Chlorzoxazone 6-Hydroxylation	Chlorzoxazone	100	6-Hydroxychlorzoxazone	27.3
CYP3A4 Testosterone 6β-Hydroxylation	Testosterone	50	6β-Hydroxytestosterone	108
CYP3A4 Midazolam 1-Hydroxylation	Midazolam	15	1-Hydroxymidazolam	73.0
AO Aldehyde Oxidase	Carbazeran	10	4-Hydroxycarbazeran	158
UGT1A1 UDP-Glucuronosyltransferase	β-Estradiol	10	β-Estradiol-glucuronide	37.5

**7-Hydroxycoumarin (7-HC), 7-Hydroxycoumarin glucuronide (7-HCG), 7-Hydroxycoumarin sulfate (7-HCS)

***Metabolite rate of formation is measured in pmol/min/10⁶ cells

Metabolic assays are run in triplicate. Activity results analyzed by HPLC-UV or LC/MS/MS validated procedures. Metabolite formation for all enzymes, except AO & UGT1A1, is measured after a 60 min. cell incubation at 37°C, 5% CO₂ and a final conc. of 1 million cells/mL. Metabolite formation for AO & UGT1A1 is measured after a 15 min. cell incubation at a final concentration of 0.25 million cells/mL.

Donor Demographics, as reported to BioIVT

Physical Attributes				Serology****		
Age	Race	Gender	BMI	EBV	RPR	CMV
58	C	Male	32.2	IgG+	Neg	Neg

****BioIVT does not routinely accept HEP C, HEP B, or HIV positive tissue. Serology results for these viruses are negative unless otherwise specified

Medical and Social History

Medical	COD:	Anoxia 2 nd to Asphyxiation
	General:	Recent flu shot
	Meds:	None
Social	Alcohol:	2 beers/day on weekends x 35 yrs
	Tobacco:	Cigars on special occasions, chewing tobacco
	Drugs:	THC on special occasions – hasn't used in 30 yrs.

Additional testing may be available. Please contact customer service.

Results for this lot have been derived through validated testing methods and confirmed by Quality Assurance.

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