

CERTIFICATE OF ANALYSIS

GENTEST® HUMAN HEPATOCYTES 10-DONOR POOLED SUSPENSION

Catalog Number	4.82034
Lot Number	240514-10
Date Released	2024 August

Storage Conditions	Store in Liquid Nitrogen
Volume	1.5mL

Post-thaw Viability and Recovery Results

Average Post-thaw Viability (%)	84
Average Viable Cells per vial (10⁶ cells)	5.1

- Hepatocytes were thawed using pre-warmed UCRM-A (Gentest® Cat. No. 4.81074) and centrifuged for 10 minutes at 100g at 4°C. After removing the supernatant, hepatocytes were re-suspended in pre-chilled WEM and counted for viability and yield using the Trypan Blue exclusion method.

Drug Metabolism Activity

Metabolic Pathway	Substrate	Substrate Conc. (µM)	Marker Metabolite	Metabolic Activity (pmol/million cells/minute)
CYP1A2	Phenacetin	100	Acetaminophen	50
CYP2B6	Bupropion	250	Hydroxybupropion	22
CYP2C8	Amodiaquine	100	Desmethyলামodiaquine	480
CYP2C9	Diclofenac	100	4-OH Diclofenac	310
CYP2C19	S-Mephenytoin	250	4-OH S-Mephenytoin	7.6
CYP2D6	Dextromethorphan	25	Dextrophan	14
CYP3A4	Midazolam	30	1-Hydroxymidazolam	120
CYP3A4	Testosterone	200	6β-Hydroxytestosterone	310
UGT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Glucuronide	420
SULT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Sulfate	49
FMO	Benzydamine HCl	250	Benzydamine-N-Oxide	720
AO	Carbazeran	10	4-Hydroxycarbazeran	74

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- Cells were suspended at a concentration of 0.25×10^6 cells/mL in WEM, then 0.1 mL of cell suspension per well was added to a TC-treated 96-well plate (250,000 cells per well), and pre-incubated at 37°C, 5% CO₂ for 5 minutes. After pre-incubation time, reaction was initiated by adding 0.1 mL of 2X substrate and incubated at 37°C for 10 minutes. Reactions were terminated with addition of 0.05 mL acetonitrile containing stable labeled internal standard, and the metabolite formation was analyzed by LC-MS/MS.

Donor Information

Specimen	Gender	Age (years)	Race	Cause of Death	BMI	Social History	Medical History	Medication given during Hospitalization
HH1013	M	22	Caucasian	Head trauma	25.2	Smoking and alcohol use; substance abuse	Asthma	n/a
HH1034	M	49	Caucasian	CVA 2 nd to ICH	29.9	Alcohol use	HTN	n/a
HH1044	M	67	Caucasian	Head trauma 2 nd to ICH	21.7	Smoking and alcohol use; substance abuse	None	n/a
HH1059	M	65	Caucasian	CVA	25.3	Smoking and alcohol use	None	n/a
HH1064	F	18	Caucasian	Head trauma 2 nd to head injury	23.2	Smoking and alcohol use	None	n/a
HH1069	F	61	African American	CVA 2 nd to ICH	41.4	Alcohol use	HTN, DM, cardiac disease	n/a
HH1077	F	41	Caucasian	CVA 2 nd to ICH	24.5	Smoking and alcohol use; substance abuse	Asthma, seizures, GERD	n/a
HH1080	F	66	Caucasian	CVA 2 nd to blunt injury	15.7	Alcohol use	Anorexia	n/a
HH1093	F	62	Caucasian	Anoxia	22.7	n/a	None	n/a
HH1095	M	41	African American	Anoxia	48.8	Smoking and alcohol use; substance abuse	HTN, CHF	n/a



HAZARD WARNING:

- This hepatocyte preparation was prepared from fresh human tissue. All donor tissues have tested negative for pathogen by PCR for the following: HIV I/II, HTLV I/II, HBV, and HCV, however we recommend this material be considered a potential biohazard.
- Donors with positive serology for CMV are identified in the donor demographic sheet with a single asterisk. Donors with CMV serology unknown are identified with a double asterisk. Donors CMV negative for serology are unmarked.

SAFETY INFORMATION:

- This product is non-hazardous, according to US OSHA hazard communication/GHS 29CFR1910.1200 therefore, a SDS (Safety Data Sheet) is not required. Handle in accordance with good industrial hygiene and laboratory safety practices.

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13 September 2024

Quality Assurance

Date

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