

## CERTIFICATE OF ANALYSIS

### GENTEST® HUMAN HEPATOCYTES 10-DONOR POOLED SUSPENSION

<b>Catalog Number</b>	4.82034
<b>Lot Number</b>	2406251-10
<b>Date Released</b>	2024 August

<b>Storage Conditions</b>	Store in Liquid Nitrogen
<b>Volume</b>	1.5mL

#### Post-thaw Viability and Recovery Results

<b>Average Post-thaw Viability (%)</b>	82
<b>Average Viable Cells per vial (10<sup>6</sup> cells)</b>	5.5

- 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	67
CYP2B6	Bupropion	250	Hydroxybupropion	46
CYP2C8	Amodiaquine	100	Desmethyলামodiaquine	630
CYP2C9	Diclofenac	100	4-OH Diclofenac	230
CYP2C19	S-Mephenytoin	250	4-OH S-Mephenytoin	8.4
CYP2D6	Dextromethorphan	25	Dextrorphan	17
CYP3A4	Midazolam	30	1-Hydroxymidazolam	80
CYP3A4	Testosterone	200	6β-Hydroxytestosterone	230
UGT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Glucuronide	260
SULT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Sulfate	66
FMO	Benzylamine HCl	250	Benzylamine-N-Oxide	780
AO	Carbazeran	10	4-Hydroxycarbazeran	85

- Cells were suspended at a concentration of  $0.25 \times 10^6$  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% CO<sub>2</sub> 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 <sup>nd</sup> to ICH	29.9	Alcohol use	HTN	n/a
HH1044	M	67	Caucasian	Head trauma 2 <sup>nd</sup> 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 <sup>nd</sup> to head injury	23.2	Smoking and alcohol use	None	n/a
HH1069	F	61	African American	CVA 2 <sup>nd</sup> to ICH	41.4	Alcohol use	HTN, DM, cardiac disease	n/a
HH1077	F	41	Caucasian	CVA 2 <sup>nd</sup> to ICH	24.5	Smoking and alcohol use; substance abuse	Asthma, seizures, GERD	n/a
HH1080	F	66	Caucasian	CVA 2 <sup>nd</sup> 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.



13 September, 2024

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**Quality Assurance**

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**Date**