

CERTIFICATE OF ANALYSIS

GENTEST® METMAX® POOLED HUMAN HEPATOCYTES

Catalog Number	4.82215
Lot Number	2405311

Storage Conditions	Store at -80°C
Date Released	2024 September

Number of Donors	10
Volume	2.5 mL
Cell concentration	2.0 x 10 ⁶ /mL

Drug Metabolism Activity

Metabolic Pathway	Substrate	Substrate Conc. (µM)	Marker Metabolite	Metabolic Activity (pmol/million cells/min)
CYP1A1	7-EROD	20	Resorufin	2.3
CYP1A2	Phenacetin	100	Acetaminophen	170
CYP2A6	Coumarin	50	7-OH Coumarin	95
CYP2B6	Bupropion	500	Hydroxybupropion	120
CYP2C8	Amodiaquine	20	Desethylamodiaquine	230
CYP2C9	Diclofenac	25	4-OH Diclofenac	380
CYP2C19	S-Mephenytoin	250	4-OH S-Mephenytoin	33
CYP2D6	Dextromethorphan	15	Dextrophan	21
CYP2E1	Chlorzoxazone	250	6-OH Chlorzoxazone	94
CYP3A4-1	Midazolam	20	1-Hydroxymidazolam	44
CYP3A4-2	Testosterone	200	6β-hydroxy testosterone	560
ECOD	7-Ethoxycoumarin	100	7-OH Coumarin	58
UGT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Glucuronide	360
SULT	7-Hydroxycoumarin	100	7-Hydroxycoumarin Sulfate	52
FMO	Benzylamine HCl	250	Benzylamine-N-Oxide	31
MAO	Kynuramine HBr	160	4-hydroxyquinoline	1200
AO	Carbazeran	10	4-Hydroxycarbazeran	80
NAT1	4-Aminobenzoic Acid	200	N-Acetyl-p-aminobenzoic acid	63
NAT2	Sulfamethazine	100	N-Acetyl-sulfamethazine	37
2J2	Astemizole	50	O-Desmethyl Astemizole	130
CES2	Irinotecan	50	SN38	1.2

Drug Metabolism Activity Assessment: Gentest® MetMax® hepatocytes were thawed in a 37°C water bath. A 1000 µL pipette (with tip) was used to pipet up and down three times to achieve homogeneity and then transferred to 1 vial of Cofactor N10/N10+, catalog 4.82212. Contents pipette mixed 2-3 times to ensure homogeneity. Substrate(s) prepared at 2X the desired final concentration. Each substrate added at a volume of 0.05 mL to a 96-well plate. Incubation initiated with addition of 0.05 mL (2x10⁶ cells/mL) Gentest® MetMax® hepatocytes combined with Cofactor N10/N10+ (100,000 hepatocytes/well) and incubated for 30 min in a 37°C, 5% CO₂ incubator and stopped with addition of 0.1 mL of acetonitrile + 0.1% Formic Acid containing internal standard. Samples centrifuged at 4000 rpm at 4°C for 20 minutes and supernatant added to injection plate. Metabolites identified using LC-MS/MS.

For product inquiries, service requests, or technical support, please contact us at (866) 458-1094 or info@dls.com

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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. The donor for the tissue used to prepare this material has been tested negative serologically for HIV I/II, HBV, and HCV. Donors with CMV serology unknown are identified with a double asterisk. Donors CMV negative for serology are unmarked and donors CMV positive for serology are marked with one asterisk.

All persons handling human hepatocytes must use Universal Precautions in accordance with the US OSHA Bloodborne Pathogens Final Standard and/or the European Council Directive on the protection of workers from risks related to exposure to biological agents at work (90/679/EEC) and its relevant European National Transpositions.

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

Quality Assurance

Date

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