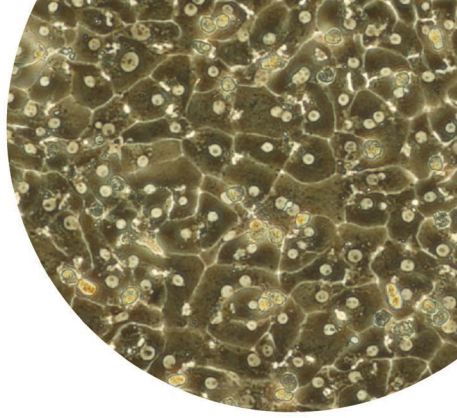
Product Characterization Sheet

Human cryopreserved hepatocytes
Lot number: Hu0948*



Donor demographics

Species	Sex	Race	Age	BMI	Smoker	Alcohol use	Drug use	Medications	Serological data	Cause of death
Human	Female	Caucasian	63 years	N/A	No	No	No	None	NA	NA

Post-thaw viability and cell quality assessment

Thawing medium used	Optimal centrifuge conditions	% Viability (post-thaw)	Viable cell yield per vial	Viability stability (% viability of suspension after 2 hr incubation)
CHRM	100 x *g* for 10 min at room temperature	94%	4.0 x 10^6	NA

Monolayer assessment

Plating medium used	Well format	Culture medium used	Optimal seeding density	Initial attachment efficiency	Monolayer confluency after 72 hr in culture
Williams' Medium E	24-well hand-coated plate	Williams' Medium E	0.75 x 10^6 cells/ml	95%	60%

Ordering Information

Product	Quantity	Cat. no.
Cryopreserved human hepatocytes	4.0 x 10^6 cells/1.5 ml vial	HMCPMS

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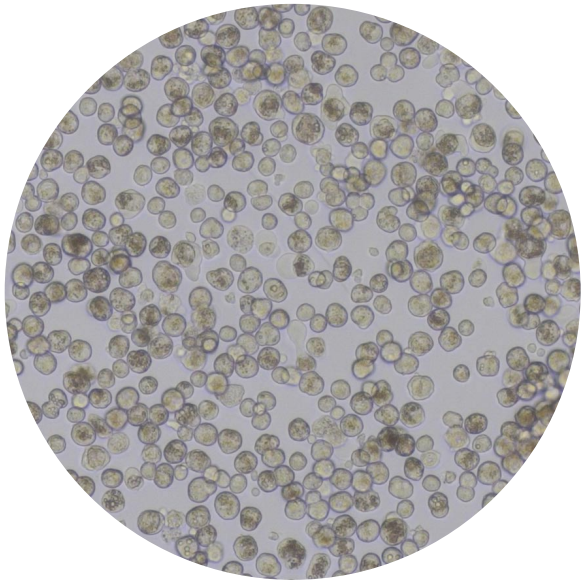
Plated metabolism (Intrinsic clearance) – µL/min/10^6 cells

Midazolam	Tolbutamide	Dextromethorphan
6.54	0.420	1.54

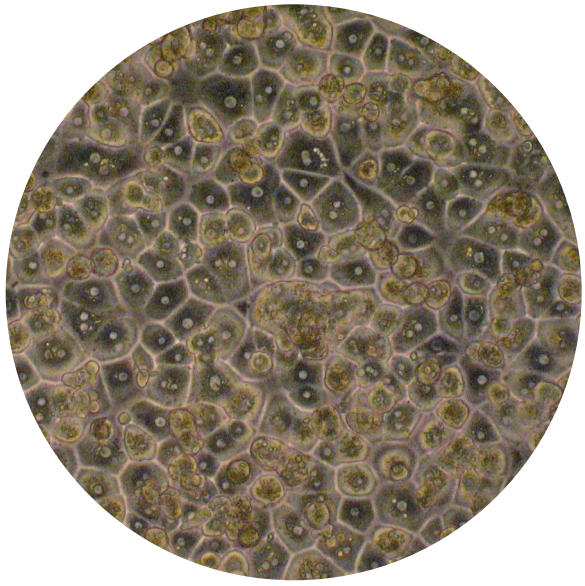
Genotyping results

Lot no.	CYP2C9	CYP2C19	CYP2D6	CYP3A5
Hu0948	WT/*3	None detected	WT/*4	*3/*3

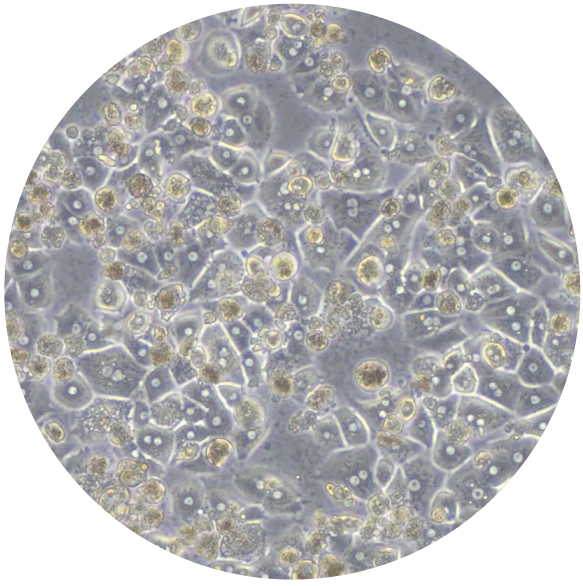
Photomicrographs of Hu0948



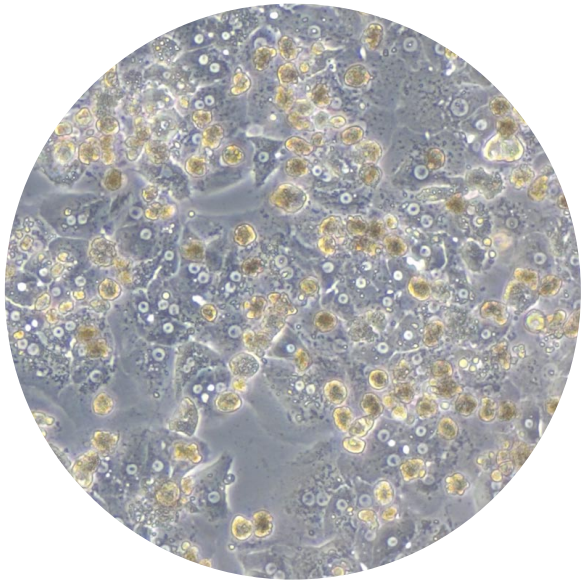
Post-thaw (10x)



5 hours after plating (24-well)



Day 2 (24-well)



Day 4 (24-well)

Metabolic assay conditions

Cryopreserved Human Hepatocytes were seeded at 0.8 x 10^6 cells/mL in 48-well coated plates and allowed to attach prior to metabolic incubations. Prototypical cytochrome P450 substrates midazolam, tolbutamide, and dextromethorphan were used to assess the enzymatic function of CYP3A4/5, CYP2C9 and CYP2D6 respectively. The concentrations and incubation times are included in the chart below. Incubations were conducted in duplicate in serum-free Williams Medium E culture medium and reactions allowed to proceed in a humidified incubator at 37°C, 95% relative humidity, and 5% CO_2 on an orbital shaker. Reactions were stopped with the addition of ice-cold acetonitrile. Well contents were stored at -70°C prior to analysis. The disappearance of parent was monitored by LC-MS/MS analysis and intrinsic clearance (CL_{int}) values determined by linear regression.

Table 2—Incubation conditions for CLint in plated cryopreserved human hepatocytes.

Substrate	Concentration (µM)	Incubation Time (h)
Midazolam	0.50	0,1,2,4,6,8
Tolbutamide	1.00	0,4,6,8,18,24
Dextromethorphan	1.00	0,1,2,4,6,8

References

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* Preliminary data, intended for marketing purposes and lot identification only. Final data will be released through ADME/Tox Quality Systems. For quality certificates, please contact your local sales representative or call 1 866-952-3559.