

## LIVERPOOL® Mixed Gender Human Hepatocytes – 50-Donor Pool, Cryopreserved

**Product: X008005 | Lot: KDH**

**Storage: ≤ -150 °C**

### Post-Thaw Viability and Yield

	Specification	Results
<b>Viability</b>	≥ 80% post-thaw viability by trypan blue exclusion	<b>87</b> %
<b>Yield</b>	≥ 5 million viable cells	<b>7.87</b> million viable cells

*Post-thaw viability and yield are an average of samples from the beginning, middle, and end of the production run. All data generated without the use of Percoll.*

\*The process for producing the LIVERPOOL® pooled human hepatocyte products is covered by one or more U.S. or foreign patents and patent applications, including U.S. Patent No. 7,604,929.

### Metabolic Activity

Enzyme & Function	Substrate	Conc. [μM]	Metabolite	Result***
<b>ECOD</b> 7-Ethoxycoumarin O-Deethylation	7-Ethoxycoumarin	75	7-HC, 7-HCG, and 7-HCS**	<b>119</b>
<b>UGT</b> 7-Hydroxycoumarin Glucuronidation	7-Hydroxycoumarin	30	7-HCG	<b>523</b>
<b>ST</b> 7-Hydroxycoumarin Sulfation	7-Hydroxycoumarin	30	7-HCS	<b>39.9</b>
<b>CYP1A2</b> Phenacetin O-Deethylation	Phenacetin	15	Acetaminophen	<b>26.8</b>
<b>CYP2A6</b> Coumarin 7-Hydroxylation	Coumarin	8	7-HC, 7-HCG, and 7-HCS	<b>146</b>
<b>CYP2B6</b> Bupropion Hydroxylation	Bupropion	250	Hydroxybupropion	<b>94.5</b>
<b>CYP2C8</b> Amodiaquine N-Desethylation	Amodiaquine	20	Desethylamodiaquine	<b>235</b>
<b>CYP2C9</b> Tolbutamide Methyl-Hydroxylation	Tolbutamide	150	4'-Methylhydroxytolbutamide	<b>48.7</b>
<b>CYP2C19</b> S-Mephenytoin 4'-Hydroxylation	S-mephenytoin	20	4'-Hydroxymephenytoin	<b>15.8</b>
<b>CYP2D6</b> Dextromethorphan O-Demethylation	Dextromethorphan	8	Dextrorphan	<b>23.9</b>
<b>CYP2E1</b> Chlorzoxazone 6-Hydroxylation	Chlorzoxazone	100	6-Hydroxychlorzoxazone	<b>26.3</b>
<b>CYP3A4</b> Testosterone 6β-Hydroxylation	Testosterone	50	6β-Hydroxytestosterone	<b>203</b>
<b>CYP3A4</b> Midazolam 1-Hydroxylation	Midazolam	15	1-Hydroxymidazolam	<b>97.3</b>
<b>AO</b> Aldehyde Oxidase	Carbazeran	10	4-Hydroxycarbazeran	<b>210</b>
<b>UGT1A1</b> UDP-Glucuronosyltransferase	β-Estradiol	10	β-Estradiol-glucuronide	<b>40.2</b>

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

\*\*\*Metabolite rate of formation is measured in pmol/min/10<sup>6</sup> 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% CO<sub>2</sub> 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

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

**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.

### Donor Demographics, as reported to BioIVT

Age/ Gender	Race	Cause of Death	BMI	Social History	Medical History	Serology****		
						EBV	RPR	CMV
1moF	Hispanic	Anoxia dt Asphyxiation	16.9	No ETOH, tobacco or drug use	No Medical History reported	IgG+	Neg	Pos
39F	Asian	CNS Tumor 2nd to Natural Causes	22.9	No ETOH, tobacco or drug use.	On and off headaches for 1 year, tremors, difficulty walking, double vision, uterine myoma removal 3-4 yrs ago, fat cyst removal from left breast 4 yrs ago.	IgG+	Neg	Pos
4M	AA	Anoxia Cerebro- vascular/ Stroke	19.7	No ETOH, tobacco or drug use.	Chronic respiratory failure, trach/vent dependence, static encephalopathy with developmental delay, epilepsy	IgG+	Neg	Pos
35M	Hispanic	2nd to Intracranial Hemorrhage/ Stroke	24.2	ETOH: 5-6 beers 2x/month x 18 yrs; no Tobacco or Drug use. Tox IgG+	Recent swollen rt leg below knee 3 wks ago, UTI w/high fever, difficulty walking, unknown weight lost in last 2 months. Meds: ABX for UTI for 10 days, vitamins.	IgG+	Neg	Pos
32M	C	Anoxia 2nd to Cardio- vascular	25.4	ETOH: 2-3 beers, 2- 3x/month x 5 yrs, quit 5 yrs ago; Tobacco: 1ppw x 5 yrs, quit 1 yr ago; Drugs: used meth last 5-10 yrs	Asthma dx 30 yrs ago - used inhaler daily, recent admit for SOB. Meds: Xopenex, unspecified meds for depression or bipolar disorder.	IgG+	Neg	Neg
51F	C	CVA	34.2	ETOH: 1-2 drinks on occasion; Tobacco: 1/2 ppd since teens - quit 18yrs ago; Drugs: THC >30yrs ago - occasionally/rarely since pregnancy. No IVDA	Adult onset asthma, anxiety. Meds: inhaler, antianxiety meds	Not reported	Neg	Pos
58F	C	CVA	26.5	ETOH: three glasses of wine daily; no drug or tobacco use	HTN occasional, no meds taken	IgG+	Neg	Neg
11F	Hispanic	Anoxia due to respiratory failure	27.2	No ETOH, tobacco or drug use.	No Medical History reported	IgG+	Neg	Neg
48M	AA	CVA 2nd to ICH	29.5	ETOH: 3 beers & 1 liquor drink 1x/week x 30yrs; No tobacco or drug use	CHF & cardiomyopathy, HTN x 10yrs, Diabetes x 10yrs	Not reported	Neg	Pos
29M	C	Head Trauma 2nd to Blunt Injury/MVA	26.0	ETOH: Drank all kinds of liquor, alcoholic beverages such as beer, vodka, etc. within last couple of yrs. Unknown amount & frequency; Drugs: Smoked marijuana on and off x 10yrs; no tobacco use	High cholesterol x11yrs, hemochromatosis diagnosed 5 yrs ago, depression 11 yrs ago, genital herpes diagnosed 5 yrs ago. Meds: None	IgG +	Neg	Pos
40M	AA	ICH	18.1	ETOH: beer - "a lot" daily; Tobacco: chew tobacco, smoked cigars; no drug use.	Cardiac arrest, alcoholism, cirrhosis (date unknown)	Neg	Neg	Pos

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

### Donor Demographics, as reported to BioIVT

Age/ Gender	Race	Cause of Death	BMI	Social History	Medical History	Serology****		
						EBV	RPR	CMV
53F	C	Anoxia 2nd to Cardiovascular	21.0	No ETOH, tobacco or drug use	Asthma, mental disability, epilepsy, petit mal seizures, sx for vagal nerve stimulator, frequent UTIs. Meds: seizure medication and others unknown	IgG+	Neg	Neg
3M	C	Anoxia/ drowning	15.5	No ETOH, tobacco or drug use	No Medical History reported. HBsAb+.	Neg	Neg	Neg
48M	AA	Anoxia 2nd to Cardiovascular	30.6	ETOH: beer weekly; Tobacco: 1/2 ppd x 30 yrs; Drugs: Smoked marijuana - not since last year	Hemodialysis for ARF, UTI; Paraplegia and colostomy sec. to GSW, obesity, obstructive sleep apnea, dermatophyte infection lower extremities. Meds: Advair, metoprolol, Norco, Soma, Lasix, potassium.	IgG+	Neg	Pos
3moF	C	Anoxia 2nd to Cardiovascular	16.0	No ETOH, tobacco or drug use	No Medical History reported. Meds: Vitamin D drops	Not reported	Neg	Neg
32M	C	ICH	23.5	ETOH: 1 beer/month x 5 yrs; no tobacco or drug use.	Chronic idiopathic thrombocytopenia, autoimmune hemolytic anemia, splenectomy 9 yrs ago, clotting factors ITP	IgG+	Neg	Pos
5M	AA	CVA 2nd to vegetation on heart valve	17.6	No ETOH, tobacco or drug use	Cardiac defects as infant - cuspid AV, AFD surgically corrected, asthma. Meds: albuterol as needed. HepB NAT neg	IgG +	Neg	Pos
60F	C	CVA 2nd to keto-acidosis	37.1	No ETOH, tobacco or drug use	Diabetes x 30yrs, insulin for 11 yrs	Not reported	Neg	Neg
62M	Asian	Other/ Natural	26.6	No ETOH, tobacco or drug use	Asthma, Diabetes. Meds: Insulin	IgG+	Neg	Pos
11moM	C	Asphyxiation	16.5	No ETOH, tobacco or drug use	No Medical History Reported	Not reported	Neg	Pos
12moF	Hispanic	Anoxia	14.2	No ETOH, tobacco or drug use	No Medical History Reported	Neg	Neg	Neg
45F	C	Anoxia 2nd to OD	33.4	ETOH: 1 beer to 1 case/wk on & off since age 18x 27 yrs; Tobacco: 1 cig - 1 ppd x 30 yrs, quit 1 year ago; Drugs: marijuana 1 / month last used 8-10 years ago, cocaine over 3-6 month period 20+ years ago - none since	HTN x 3yrs - compliant, depression, anxiety, hysterectomy, GERD x 3 yrs. MEDS: acid reflux, BP	Not reported	Neg	Pos
2M	C	Head trauma from MVA	17.3	No ETOH, tobacco or drug use	No Medical History Reported	IgG+	Neg	Pos
3M	C	MVA	18.4	No ETOH, tobacco or drug use.	No Medical History Reported	IgG+	Neg	Pos

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

X008005.5 / Page 3 of 6

### Donor Demographics, as reported to BioIVT

Age/ Gender	Race	Cause of Death	BMI	Social History	Medical History	Serology****		
						EBV	RPR	CMV
41M	C	Drug Intoxication	24.7	ETOH: 3 beers monthly x 26 yrs; Tobacco: 0.5ppd x 6 yrs; Drugs: used cocaine and crack x 1-2 yrs - last used 1 month ago, used Percocet and pills x 12 yrs, smoked marijuana, smoked heroin x 12 yrs.	Asthma since childhood, ACL repair 8 yrs ago, umbilical hernia repair at 6 mos old, poor vision with laser surgery correction bilaterally, overdose 10 yrs ago. Meds: Albuterol, Singulair	IgG+	Neg	Neg
58M	AA	Anoxia/ Cardio-vascular	27.7	ETOH: 5+ drinks on weekends x 24 yrs; Tobacco: 1/2ppd x 24 yrs, quit 3 months ago; no drug use.	CHF, Hypertension	IgG+	Neg	Pos
7daysF	C	Anoxia	13.1	No ETOH, tobacco or drug use.	41wk gestation - C-section for fetal bradycardia	Neg	Neg	Pos
10moM	AA	Head trauma 2nd to Blunt Injury/MVA	22.7	No ETOH, tobacco or drug use.	No Medical History Reported	IgG+	Neg	Pos
51M	C	CVA	31.0	Tobacco: 1 ppd; no ETOH and drug use.	COPD, CAD	IgG+	Neg	Neg
60F	C	CVA/Stroke 2nd to ICH/Stroke	21.6	No ETOH, tobacco or drug use.	Sinus related headaches x 10 yrs, gallbladder sx 23 yrs ago	IgG+	Neg	Pos
35F	C	Anoxia	25.4	ETOH: 1 beer special occasionally x 15+ years; Drugs: Ecstasy and smoked THC (over 4 year period while in college) - last used 10+ yrs ago; no tobacco use.	Medical anorexia, anxiety, hydrocephalus, PE and brain aneurysm, VP shunt, clipping and coiling of aneurysm 6 yrs ago.	Neg	Neg	Pos
57F	C	CVA	27.6	ETOH: Social; Tobacco: ex-smoker x 1yr; no drug use	HTN 0-5yrs	Not reported	Not reported	Pos
34F	Hispanic	Stroke	33.6	No ETOH, tobacco or drug use	Cardiac arrest, seizures for several months, hemorrhoids, gestational diabetes last pregnancy (gave birth 5 months ago). Meds: multi vitamins	Not reported	Neg	Pos
48F	O	Trauma; 2nd to MVA (Semi T-Bone)	21.0	ETOH: mild, many years ago; no tobacco or drug use	Diverticulitis w/surgery. Donor is Polynesian.	Not reported	Neg	Pos
52M	C	SIGSW	30.4	ETOH: 1 liter Vodka 7- 8 yrs daily; Tobacco: 2 ppd x 35 yrs; no drug use.	HTN x 15 yrs w/ meds, bipolar, anxiety attacks	Not reported	Neg	Pos
68F	C	ICH	20.5	ETOH: 3 vodka drinks daily x 30 yrs; Tobacco: 1 ppd x 40 yrs; no drug use	Seizures, stroke, external lupus on skin, Alzheimer's dx 1 1/2 yrs ago	Not reported	Neg	Not reported
6daysF	C	Anoxia, Asphyxiation	15.9	No ETOH, tobacco or drug use	No medical history reported	IgG+	Neg	Pos

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

### Donor Demographics, as reported to BioIVT

Age/ Gender	Race	Cause of Death	BMI	Social History	Medical History	Serology****		
						EBV	RPR	CMV
71F	C	ICH	45.6	ETOH: 3 glasses wine QDx50 yrs; Tobacco - quit 25 yrs ago ; no drug use	Knee replacement, hysterectomy, 5 yrs ago long plane flt-DVT in leg - progressed to PE. Meds: Coumadin, Paxil	Not reported	Neg	Pos
68F	C	CVA/Stroke	28.6	ETOH: occasionally beer, quit; Tobacco: couple of cigarettes/day since teen, quit; no drug use.	High cholesterol, bipolar disorder. Meds: Atorvastatin, Abilify	IgG+	Neg	Pos
1M	C	Anoxia 2nd to Cardiovascular	19.4	No ETOH, tobacco or drug use	Anemia, Hydrocephalus at birth (shunt placed), non-traumatic grade 4 IVH at birth, hydronephrosis, Patent Ductus Arteriosus, prematurity, epilepsy, recent ear infection, sore throat/bronchitis - abx and nebulizer x 1wk. Meds: Phenobarbital, zofran.	Neg	Neg	Neg
48F	Hispanic	Cerebrovascular/ Stroke 2nd to ICH	34.4	ETOH: 1 beer 3-4x/yr x 20+ yrs; no tobacco or drug use ETOH: 12 shots of vodka, beer, hard liquor daily x 40 yrs; Drugs: Cocaine in early 20s and 30s on weekends (again 3 yrs ago), marijuana 1-2 joints on weekend x 20 yrs – quit; no tobacco use.	No medical history. Meds: Herbs in tea form to improve circulation	IgG+	Neg	Pos
52M	C	Head Trauma 2nd to Blunt Injury	18.1		Severe seizure for last 5 yrs, delusional, hallucinations due to brain injury after fight 5 yrs ago, difficulty walking due to frostbite and poor hygiene. Meds: Unknown seizure meds.	IgG+	Neg	Pos
57M	C	CVA 2nd to ICH	29.4	ETOH: 1 beer/yr adult life; no tobacco or drug use.	HTN x 5yrs, DM Type II x 5yrs - not controlled due to pt's diet - unknown if compliant w/meds. Meds: HTN Meds, Insulin Metformin	IgG +	Neg	Neg
38F	Hispanic	CVA 2nd to Stroke	22.3	No ETOH, tobacco or drug use	CVA, seizures, anemia, cardiomyopathy, dyslipidemia, Addison's disease, IDDM, gastroparesis, HTN, CRI. Meds: Lasix, Dilantin, Coreg, Lisinopril, Hydrochlorothiazide, Nifedipine, Nortriptyline, Florinef, Reglan	Not reported	Neg	Pos
58F	Asian	CVA/ICH Anoxia 2nd to Cardiovascular	31.6	ETOH: Wine up to 3/yr, 1-2 glassed per event; no tobacco or drug use.	Asthma when young (resolved), hypertension (unknown duration), liver disease - chronic hepatitis (moderate, portal and indication of Fibrosis)	Not reported	Neg	Neg
53F	Hispanic		33.7	No ETOH, tobacco or drug use	HTN, ALS, Cholecystectomy	IgG +	Neg	Pos

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

### Donor Demographics, as reported to BioIVT

Age/ Gender	Race	Cause of Death	BMI	Social History	Medical History	Serology****		
						EBV	RPR	CMV
64M	C	CVA	26.8	ETOH: 2-4 drinks daily x 20yrs - quit 17 yrs ago; Tobacco: 3/4 ppd x 40 yrs; Drugs: Snorted Meth 2x/daily x 6 yrs - quit 2 yrs ago	Hypertension x 6 yrs with no meds, osteosarcoma at age 6 - surgically removed.	IgG+	Neg	Pos
45M	AA	CVA/Stroke	25.1	No ETOH, tobacco or drug use	ESRD, MI, stents, T1D x 32 yrs, dialysis for past 4 yrs, angioplasty. Meds: Insulin, other meds unknown	IgG+	Neg	Pos
39M	C	Anoxia 2nd to Drug Intoxication	29.8	ETOH: 6 beers daily x 20 yrs; Tobacco: 2ppd x 25 years; Drugs: recreationally used cocaine and prescription pills.	Smokers cough, cyst above coccyx removed	IgG+	Neg	Neg
35F	C	Anoxia 2nd to OD	26.5	ETOH: infrequently; Tobacco: 1/2-1 ppd x 19 yrs; Drugs: smoked meth twice in past yr, prescription drug abuse	Cardiac disease	IgG+	Neg	Pos

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

As of March 5<sup>th</sup>, 2018, "BioIVT" will replace the current brand of BioreclamationIVT and those of each of its affiliates and subsidiaries: IVT Holdings Inc., Asterand Bioscience, Inc., Asterand UK Acquisition limited, Asterand US Acquisition Corporation, Labquote.com LLC, ILSBio LLC, Seratrials LLC, Sera Laboratories International Ltd., Translational Cell Science LLC, Bioreclamation-IVT India Private Limited, In Vitro Inc., In Vitro GmbH, Qualyst Holdings LLC, Qualyst Transporter Solutions LLC.

X008005.5 / Page 6 of 6

**North America &  
Asia Pacific** ☎ 410-394-7600  
@ customerservice@bioivt.com  
Baltimore, MD 21227, U.S.A.

**Europe, Middle East  
& Africa** ☎ 32 (0) 2 808 8278  
@ ivtcs@bioivt.com  
Brussels, Belgium