XENOTECH
A BioIVT Company

Data Sheet
Certificate of Analysis

# CryostaX

## Single-Freeze Pooled Cryopreserved Human Hepatocytes

## HPCH20-50 Lot No. 2310103

Pool of 20

Assured Minimum Yield: $5.0 \times 10^6$ cells per vial
Viability: 74%

| *Enzyme* | *Marker Substrate Reaction* | *[S] (µM)* | *Rate (pmol/million cells/min)* |
|---|---|---|---|
| CYP1A2 | Phenacetin *O*-dealkylation | 100 | 71.9 ± 4.1 |
| CYP2A6 | Coumarin 7-hydroxylation | 50 | 67.3 ± 1.0 |
| CYP2B6 | Bupropion hydroxylation | 500 | 84.8 ± 5.7 |
| CYP2C8 | Amodiaquine *N*-dealkylation | 20 | 476 ± 36 |
| CYP2C9 | Diclofenac 4'-hydroxylation | 100 | 264 ± 12 |
| CYP2C19 | *S*-Mephenytoin 4'-hydroxylation | 400 | 10.4 ± 0.6 |
| CYP2D6 | Dextromethorphan *O*-demethylation | 80 | 65.1 ± 0.5 |
| CYP2E1 | Chlorzoxazone 6-hydroxylation | 500 | 141 ± 3 |
| CYP3A4/5 | Testosterone 6β-hydroxylation | 250 | 333 ± 15 |
| CYP3A4/5 | Midazolam 1'-hydroxylation | 30 | 67.5 ± 3.0 |
| UGT | 7-Hydroxycoumarin glucuronidation | 100 | 478 ± 25 |
| SULT | 7-Hydroxycoumarin sulfonation | 100 | 22.7 ± 1.4 |

To measure cytochrome P450 (CYP), UDP-glucuronosyl transferase (UGT) and sulfotransferase (SULT) activities, hepatocytes ($1 \times 10^6$ cells/mL) in suspension were incubated in triplicate at 37 ± 2°C for 30 minutes in OptiIncubate and marker substrate, at the final concentrations indicated. Metabolite formation was determined by validated LC-MS/MS methods with deuterated metabolites as internal standards.

### Uptake Activity Data

| *Uptake Transporter* | *Marker Substrate* | *[S] (µM)* | *Rate (pmol/million cells/min)* |
|---|---|---|---|
| OATP1B1 | Estrone sulfate | 1 | 27.0 |
| OATP1B3 | CCK-8 | 1 | 7.6 |
| OCT1 | MPP+ | 1 | 3.1 |
| NTCP | TCA | 1 | 4.8 |

To measure uptake activities, hepatocytes ($0.5 \times 10^6$ cells/mL) in suspension were incubated in triplicate at 4°C ± 2°C and 37°C ± 2°C for 1 minute in Krebs-Henseleit buffer and marker substrate, at the final concentrations indicated. Uptake of substrate was measured by scintillation counter.

### Donor Information

| | |
|---|---|
| **Gender:** | Males (10), Females (10) |
| **Age:** | 7-65 years of age |
| **Race:** | Caucasian (18), African American (2) |
| **Cause of Death:** | Cerebrovascular accident (7), Anoxia (11), Head trauma (2) |
| **Antibody to Cytomegalovirus (CMV):** | Positive (10), Negative (9), Not Determined (1) |

All donors tested negative for Human Immunodeficiency Virus (HIV), Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus, and Rapid Plasma Reagin.

**Store in liquid nitrogen, vapor phase**

CAUTION: This sample should be considered as a potential biohazard and universal precautions should be followed. Intended for *in vitro* use only.

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**This data sheet serves as a Certificate of Analysis and has been approved by Stephanie Helmstetter, Assistant Director.**
**Signature and Date:** Stephanie Helmstetter 19 April 2023