

Certificate of Analysis

HepaRG™ Cells, 1 Vial



Part Number: HPRGC10

Lot Number: 1464818

Immediate Storage: Liquid nitrogen or thaw for immediate use.

Shipping Conditions: dry ice overnight (or liquid N₂ followed by dry ice overnight)

5791 Van Allen Way

Carlsbad, CA 92008

Phone: 760.603.7200

Fax: 760.602.6500

www.lifetechnologies.com

Description:

HepaRG™ cells are terminally differentiated hepatic cells derived from a human hepatic progenitor cell line that retains many characteristics of primary human hepatocytes. HepaRG™ cells exhibit many characteristics of primary human hepatocytes, including morphology and expression of key metabolic enzymes, nuclear receptors, and drug transporters. Unlike HepG2 and Fa2N-4 cells, HepaRG™ cells have high P450 activity and complete expression of all nuclear receptors.

The cells for lot 1464818 were derived from the HepaRG™ Cell Line. The cell line was obtained through license from BIOPREDIC International, for research purposes. HepaRG™ is a trademark of BIOPREDIC International.

Quantity of Cells: ~ 10,000,000 cells/vial

Cell Density: 10,000,000 cells/mL

General Specifications:

Human, Adult, Female, Hepatocytes, Single Donor, non-cGMP Compliant

Storage and Handling:

After shipment either thaw for immediate use or store in liquid nitrogen.

Cells stored for more than 1 day at -80°C quickly lose viability.

Caution:

Not intended for human or animal diagnostic or therapeutic uses. Users should treat all human and animal cells as potential pathogens. Wear protective clothing and eyewear. Practice appropriate disposal techniques for potentially pathogenic or biohazardous materials.

Biosafety:

Contact the in-house Safety Officer for information on safe handling of human cell products, universal precautions, and for information on what to do in case of exposure. For recommended post exposure procedures, call the Centers for Disease Control (CDC) Information line at +1 800 232 4636.

QUALITY ASSURANCE

Isolation Results:

Date of cell freezing: 09/Dec/2013

Cell Viability: ≥80% **94%**

Pathogen Testing:

The cell line has tested negative for the following viruses as determined by PCR.

HEPATITIS B	HEPATITIS C	HIV1
negative	negative	negative

Mycoplasma Testing: No mycoplasma detected.

Specific Activity Results:

Specific Activity was evaluated on cells in suspension for a 1 hour incubation. Metabolites formed were measured by LC-MS/MS. Results are recorded as pmol/(min*million cells).

PARAMETER	ENZYME	RESULT
Phenacetin O-deethylase activity	CYP1A2	18
Bupropion hydroxylase activity	CYP2B6	19
Midazolam 1'-hydroxylase activity	CYP3A4/5	54

Induction Results:

Induction performed in Induction Media with prototypical inducers. Specification and result is based on fold over control (FOC).

INDUCERS	PARAMETER	ENZYME	RESULT
Omeprazole (50 µM)	Phenacetin O-deethylation	CYP1A2	4
Phenobarbital (1 mM)	Bupropion Hydroxylation	CYP2B6	5
Rifampicin (10 µM)	Midazolam Hydroxylation	CYP3A4/5	8

For questions, please contact our Technical Support Team

N. Am Ph#: 800-955-6288 or INTL Ph#: 760-603-7200 Select option 5, ext. 40266 Email: hepaticproducts@invitrogen.com.

Certificate of Analysis**Part Number:** HPRGC10, **Lot Number:** 1464818**Genotyping Results:**

Results for each single nucleotide polymorphism (SNP) were obtained by Biopredic International in collaboration with N. Picard at Limoges Hospital. Key: wt = wild-type, mt = mutation

CYP2D6					CYP3A4
*2 (2850C>T)	*3 (2549delA)	*4 (1846G>A)	*7 (2935A>C)	*10 (100C>T)	*1B (392G>A)
*2/wt	wt/wt	wt/wt	wt/wt	wt/wt	wt/wt

OATP1B1 (=OATP2)	OATP1B3 (=OATP8)	MRP2		
*5 (521T>C)	334T>G	-24C>T	1249G>A	3972C>T
*5/wt	wt/wt [^]	wt/wt	wt/mt	wt/mt

[^]: wt=G (T=minor allele in Caucasians)



Nicole Carlson, QA Engineer

Date: 06/Mar/2014

HepaRG™ is a trademark of BIOPREDIC International.

LIMITED USE LABEL LICENSE HepaRG™ Cells are patented and their use is strictly limited; consider the cells as a single-use, disposable product that must be destroyed upon conclusion of a study or experiment. Propagating, reproducing, cloning, subcloning or any other use of the cells following the conclusion of a study is prohibited. Use of the cells to produce or manufacture commercial products for general sale or for use in the manufacture of products intended for general sale is prohibited. Transfer of the cells to anyone not employed within the same organization, whether for financial benefit or not, is also prohibited.

For Research Use Only. Not for use in diagnostic procedures.

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