

Certificate of Analysis

Submitted by:

Quality Control Personnel ID No.: 0016 Quality Assurance Personnel ID No.: 0016

Applied Biological Materials Inc.

1-3671 Viking Way, Richmond, BC, CANADA V6V 2J5

Product Description

Product Name:	Enhanced Primary Human Hepatocytes – 5 Million	
Cat. Number:	T5996	
Lot Number:	10-13	
Quantity:	1 vial (Cryopreserved)	
Donor Information:	Female, 48 years old, Caucasian	
Evaluation Medium:	TM103	
Serology:	CMV (-), HIV (-), HBV (-), HCV (-)	
Hepatic Markers via	AAT (+), AFP (-), CK8 (+), CK18 (+), HSA (+)	
Immunofluorescence Staining:		
Hepatic Markers via Periodic Acid-Schiff (PAS) Staining:	Glycogen Storage (+)	
CYP450 Activities and Induction:	HPLC Method	
Viability:	>70%	
Cell Count:	5.0 x 10 ⁶ cells/ ml	
Seeding Density:	10,000 cells/cm ²	

^{*}Using **abm**'s standardized culture system and procedures; the stated value may vary depending on end user's culture conditions.

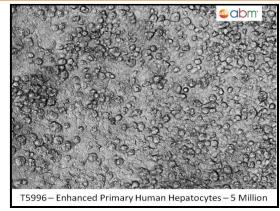
Microbial Test Results:

	Detection Method	Specification Range	Results
Fungal	Direct Culture	Negative	Pass
Bacterial	Direct Culture	Negative	Pass
Mycoplasma	PCR	Negative	Pass

Approved by:

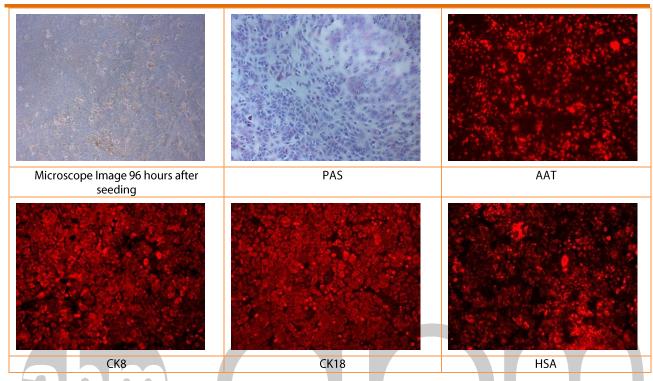
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Date: June 16th, 2017





Hepatic Markers



CYP450 Activities and Induction Results

Basal CYP450 Activities	Method	Results
CYP1A2 [pmol/min/mg]	HPLC (Phenacetin O-deethylation)	3.3
CYP2B6 [pmol/min/mg]	HPLC (Bupropion hydroxylation)	40.3
CYP2C9 [pmol/min/mg]	HPLC (Tolbutamide 4-hydroxylation)	91.8
CYP3A4 [pmol/min/mg]	HPLC (Testosterone 6ß-hydroxylation)	21.4

CYP450 Induction Response	Method	Results
CYP1A2 [fold]	HPLC (Phenacetin <i>O-</i> deethylation; Prototypical Inducer: 50μM Omeprazole)	7.3
CYP2B6 [fold]	HPLC (Bupropion hydroxylation; Prototypical Inducer: 2mM Phenobarbitone)	5.1
CYP2C9 [fold]	HPLC (Tolbutamide 4-hydroxylation; Prototypical Inducer: 20μΜ Rifampin)	2.8
CYP3A4 [fold]	HPLC (Testosterone 6ß-hydroxylation; Prototypical Inducer: 20µM Rifampin)	8.2