Hep-G2

Assay Ready Cells

Certificate of Analysis

Lot-N°: **92-200904VE01**

BATCH SPECIFICATIONS

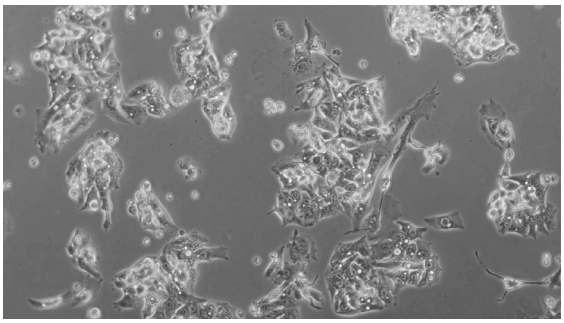
Cell Designation:	Hep-G2 cell type	Source:	ID0080
Cat-N°:	RE561	Lot-N°:	92-200904VE01
Packaging Unit:	2.5 million cells / vial	Assay Medium:	C
Passage:	14	Storage:	below -150°C (e.g. liN_2)
Approval Date:	18.09.2020	Approved by:	
Expiry Date:	04.09.2022		

Susan Ciura (Head of Quality Control)

QUALITY CONTROL

	Batch Results	Specification Limits
Cell Count	3.25E+06	≥ 90 % of nominal cell count
Homogeneity (cell count)	99 %	≤ 90 %
Viability (after thawing)	93 %	≥ 90 %
Aggregation	1.9	≤ 2.0
Debris Ratio	0.8	≤ 1.0
Proliferative Capacity	100 %	≥ 70 %
Sterility (bacteria, yeast, fungi)	passed	sterile after 4 days
Sterility (mycoplasma)	passed	negative by PCR
Morphology	passed	unaltered to reference

MORPHOLOGY:



Morphology of Hep-G2 assay ready cells

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METHODS

Cell Viability Parameters:	Viability parameters (viable cell count after thawing, grade of aggregation, percentage of debris) were determined from a pooled sample (SOP-2015-02). Briefly, assay ready cells were thawed in a water bath. 50 µl of each sample were pooled, diluted 1:1000 in CASY Ton buffer and measured (3 replica) in a CASY TT automatic cell counter. Vial to vial variation was determined in a plate-based viability assay. Equal aliquots of each cell samples were dispensed into a 96 well-plate. A cellular dye was added to the well to obtain fluorescent signal which is proportional to the viable cell count.
Proliferative Capacity:	1,0E+04 cells from the assay ready cell samples and from a reference of a continuously passaged culture were seed in a 96-well plate (8 replica each). After 48 hours of cultivation the proliferation of the cells was determined by addition of a metabolic cell dye (Resazurin). The proliferative capacity of the assay ready cells is calculated in percent of the exponentially growing reference. (SOP-2017-03).
Sterility Testing:	Assay ready cells were seed in two specific bacteria growth brothes (Tryptic Soy Broth for aerob and Thioglycollate broth for anaerob conditions) and cultivated over a course of 14 days. After day 1, 4, 7 and 14 the cultures were analyzed microscopically for cell growth, cell morphology, and incidences of contamination (bacteria, yeast, or fungi). For mycoplasma testing from a three days old, sub-confluent culture 500 µl of the supernatant was taken and analyzed by PCR using a Mycoplasma detection kit (Minerva). Assay was performed according to the manufacturer protocol (SOP-2015-06).

LIMITED USE

The product is sold under the terms of a Limited Use Label License attached to the product. By breaking the seal of the product package, the user explicitly agrees to the license terms. Assay Ready Cells are for immediate assay use only. The user shall not propagate, passage, or refreeze the cells.