CERTIFICATE OF ANALYSIS

instaCELL KeratinoSens® Assay Kit

CatN°: SF220-01
Lot#: KS-221114
Expiry Date: 12.04.2024

PRODUCT DEFINITION

Test kit to assess the skin sensitization potential of chemicals and leachables by their application to cultures of KeratinoSens® cells and the subsequent determination of cell viability.

QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	**1.4E+06**	1.0E+06<>1.5E+06
Homogenity (cell count)	**96%**	≥ 90%
Viability (after thawing)	**97%**	≥ 90%
Proliferative Capacity	**70%**	≥ 70%
Debris/Cell Ratio	**0.2**	≤ 1.0
Aggregation	**1.2**	≤ 2.0
Sterility (bacteria, yeast, fungi)	**passed**	negative after 7 days
Sterility (mycoplasma)	**passed**	negative by PCR
Morphology	**passed**	unalterd to reference
EC1.5 DNCB	**2.1 µM**	≤12.5 µM
EC1.5 EGDMA	**46.7 µM**	30 - 100 µM
EC1.5 Lactic Acid	**≥ 1000 µM**	≥ 1000 µM

KIT CONTENT

	Cat-N°	Lot#	Storage	Quantity
Recovery Buffer H	MD178-01	91-220915NR02	-20°C	2
Assay Buffer H	MD378-06	91-220914NR01	-20°C	2
Assay Medium H	MD478-06	91-220915NR01	-20°C	1
Positve Control (25mM EGDMA)	RX507-01	91-220916NR01	-20°C	2
Resazurin Solution	RX718-01	91-220727MD01	-20°C	1
Promega, OneGlo™	KR005-04	524384	-20°C	1
Assay Ready KeratinoSens Cells	RE242K	92-220412NR01	< -140°C	1
Assay Ready KeratinoSens Cells	RE242K	92-220412NR02	< -140°C	1
96-well Assay Plate	ZG02-12	1348485	RT	2

Sterility was analyzed by microscopic/visual control after seven days according to sterility testing. Functionality of the content was tested by performing the assay with all listed batches.

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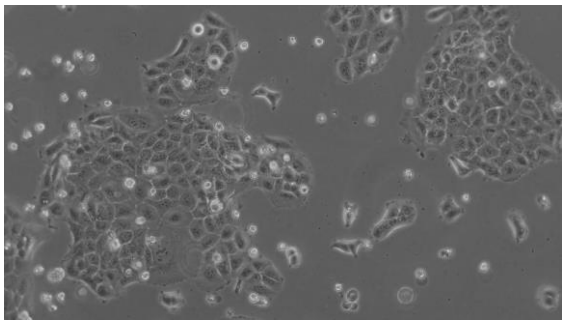
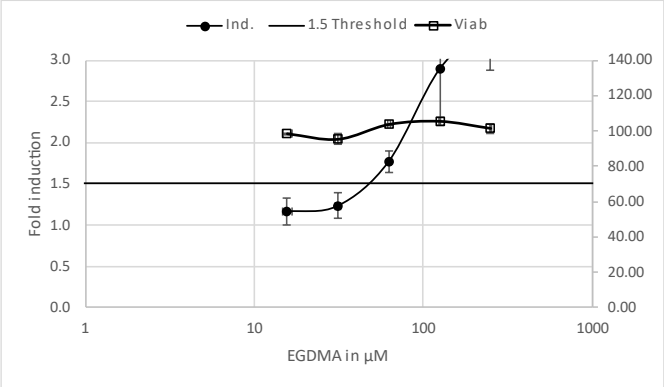
MORPHOLOGY:



Morphology of KeratinoSens Assay Ready Cells

KERATINOSENS ASSAY:



Dose response of positive control Ethylenglykoldimethacrylat (EGDMA) performed according to the assay protocol. Fold-Induction and Viability

METHODS

Cell Viability Parameters (cell count, viability, aggregation, amount of debris) are determined in a CASY TT automatic cell counter. Homogeneity is analyzed in a plate-based assay.

Proliferative Capacity compares the mean growth rates of freshly thawed cells in relation to exponentially growing cells over 72 hours.

Sterility is tested by inoculation of aerob and anaerob growth broths (Tryptic Soy and Thioglycollate for bacteria, yeast and fungi) with samples and cultivation over a course of 7 days.

Mycoplasma are detected by PCR using a mycoplasma detection kit.

Species Identity is tested by amplification of a specific fragment of 18S rRNA coding region via multiplex PCR (dog, mouse, Chinese hamster, human, monkey, rat, pig and bovine).

Human Cell Identity is performed by STR analysis (DNA fingerprinting). Markers: D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D21S11, CSF1PO, FGA, TH01, TPOX and vWA, DYS391, D2S441, D1S1656, D2S1338, Y indel, D12S391, D19S433, D22S1045, D10S1248, SE33, Amelogenin.

Potency Assay: The assay was performed according to the instaCELL protocol.

LIMITED USE

The product is provided under the terms of a limited use license provided with the kit. By breaking the sealed bag, the user is explicitly accepting the terms for limited use. The cell line uses Luciferase technology from Promega (U.S. Pat No. 8008006 & EU Pat. No. 1341808B1). The Kit may only be used under the terms of a limited use license which is attached as part of this kit.

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