

CERTIFICATE OF ANALYSIS

instaCELL Mikronucleus Assay Kit

CatN°: SF120-01
Lot#: MN-230222
Expiry Date: 30.06.2024
Rev.No. 01 / 13.11.2023

PRODUCT DEFINITION

Test kit to assess the genotoxic effect of chemicals and leachables by their application to cultures of V79 cells and the subsequent determination of number of nuclei and cell viability.

QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	5.83E+05	4E+05<>6E+05
Homogeneity (cell count)	97%	≥ 90%
Viability (after thawing)	98%	≥ 90%
Proliferative Capacity	90%	≥ 70%
Debris/Cell Ratio	0.1	≤ 1.0
Aggregation	1.6	≤ 2.0
Sterility (bacteria, yeast, fungi)	passed	negative after 7 days
Sterility (mycoplasma)	passed	negative by PCR
Morphology	passed	unaltered to reference
Responsivity (0.6µM Mitomycin C)	21 micronuclei	≥ 10 micronuclei

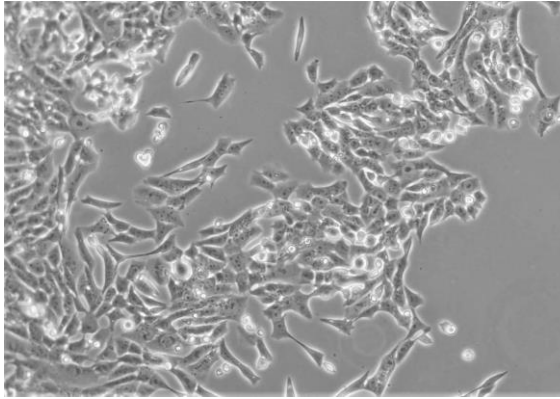
KIT CONTENT

	Cat. N°	Lot#	Storage	Quantity
Recovery Buffer B	MD125-01	91-221119ML02	-20°C	1
Assay Buffer B	MD325-06	91-230203ML01	-20°C	1
Assay Medium B	MD425-06	91-230203ML02	-20°C	1
Serva, Mitomycin C	002980550	220330	RT	1
Flourosshield™	RX702-01	91-221207ML01	4°C	1
Assay Ready V79 Cells	RE781K	92-200421VE01	< -140°C	1
3-well Ibidi chamber	80381	220111/3	RT	5

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.



MORPHOLOGY:



Morphology of V79 Assay Ready Cells

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.

