CERTIFICATE OF ANALYSIS

instaCELL Cytotoxicity Assay Kit

CatN°: SF020-01
Lot#: CX-231204
Expiry Date: 08.07.2025

PRODUCT DEFINITION
Test kit to assess the cytotoxicity of chemicals and leachables by their application to cultures of mammalian cells and the subsequent determination of cell viability.

QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	**1.07E+07**	9.00E+06 < result < 1.20E+07
Homogenity (cell count)	**99 %**	≥ 90%
Viability (after thawing)	**97 %**	≥ 90%
Proliferative Capacity	**100 %**	≥ 70%
Debris/Cell Ratio	**0.1**	≤ 1.0
Aggregation	**1.3**	≤ 2.0
Sterility (bacteria, yeast, fungi)	**passed**	negative after 7 days
Sterility (mycoplasma)	**passed**	negative by PCR
Morphology	**passed**	unalterd to reference
Cytotoxicity Assay (max signal)	**20439 RFU**	15000 RFU < result < 30000 RFU
Cytotoxicity Assay (min signal)	**1229 RFU**	1000 RFU < result < 4000 RFU
Cytotoxicity Assay (IC50)	**Sodium Selenite: 2.4E-05 M**	1.0E-05 M < x < 2.0E-04 M
Cytotoxicity Assay (Z')	**0.96**	> 0.5

KIT CONTENT

	Cat-N°	Lot#	Storage	Quantity
Recovery Buffer A	MD163-01	91-231023ML01	-20°C	1
Assay Buffer A	MD363-06	91-231026ML02	-20°C	1
Assay Medium A	MD463-01	91-231019ML01	-20°C	1
Cytotoxic Control	RX501-01	91-231023ML02	-20°C	1
Resazurin Solution	RX718-01	91-231018ML01	-20°C	1
96-well Assay Plate	ZG14-08	3021921	RT	1
Assay Ready L-929 Cells	RE772	92-230708ML01	< -140°C	1

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.

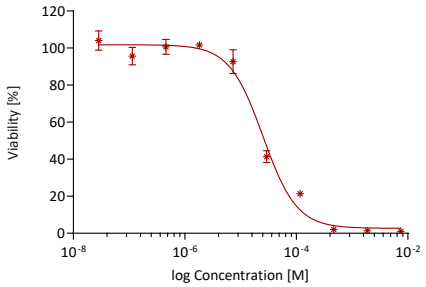
acCELLerate GmbH
Osterfeldstraße 12-14
22529 Hamburg, Germany

managing directors
Dr. Oliver Wehmeier
Dr. Alexander Loa

bank account details
Commerzbank Hamburg AG
IBAN DE06200400000327703500
BIC COBADEHHXXX

company details
VAT ID No. DE294633185
register number: HRB 131393
registered seat: Hamburg, Germany

CYTOTOXICITY ASSAY



Dose response of the Cytotoxic Control (Sodium Selenite) performed according to the assay protocol.

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.

Cytotox Assay: The assay was performed according to the instaCELL assay 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.

acCELLerate GmbH
Osterfeldstraße 12-14
22529 Hamburg, Germany

managing directors
Dr. Oliver Wehmeier
Dr. Alexander Loa

bank account details
Commerzbank Hamburg AG
IBAN DE06200400000327703500
BIC COBADEHHXXX

company details
VAT ID No. DE294633185
register number: HRB 131393
registered seat: Hamburg, Germany