

CERTIFICATE OF ANALYSIS

instaCELL Phospholipidosis Assay Kit

CatN°: SF130-01

Lot#: PD-230222

Expiry Date: 14.10.2024

Re-tested: 14.04.2024

PRODUCT DEFINITION

Test kit to screen for drug induced accumulation of phospholipids by their application to cultures of mammalian cells and the subsequent determination using fluorescent labeled phospholipids.

QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	3.3E+06	3.1E+06 < result < 3.9E+06
Homogeneity (cell count)	99%	≥ 90%
Viability (after thawing)	93%	≥ 85%
Proliferative Capacity	100%	≥ 70%
Sterility (bacteria, yeast, fungi)	passed	negative after 7 days
Sterility (mycoplasma)	passed	negative by PCR
Morphology	passed	unaltered to reference
Ratio Positive Control	13.7	> 3

KIT CONTENT

	Cat-N°	Lot#	Storage	Quantity
Recovery Buffer C	MD148-01	91-221124ML01	-20°C	1
Assay Buffer C	MD348-06	91-220705MD01	-20°C	1
Assay Medium C	MD448-01	91-221028NR01	-20°C	1
Positive Control (Sertraline)	RX505-01	91-220309MD01	-20°C	1
Negative Control (Cyclosporine A)	RX506-01	91-220325NR03	-20°C	1
PLD-Staining Solution	RX720-01	91-220815NR01	RT	1
Assay Ready Hep-G2 Cells	RE561K	92-221126ML01	< -140°C	1
96-well Assay Plate	ZG14-08	3021921	RT	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.



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.

Phospholipidosis 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.

