

CERTIFICATE OF ANALYSIS

instaCELL pyrogen detection kit

CatN°: SF240-01

Lot#: PD-240226

Expiry Date: 26.02.2026

PRODUCT DEFINITION

Test kit to assess the pyrogenity of chemicals and leachables by their application to cultures of THP-1 derived macrophages and the subsequent determination of TNF- α concentration. 1.5

QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	1.2E+07	9.0E+06 \leq result \leq 1.2E+07
Homogeneity (cell count)	97 %	\geq 90%
Viability (after thawing)	94 %	\geq 90%
Sterility (bacteria, yeast, fungi)	passed	negative after 7 days
Sterility (mycoplasma)	passed	negative by PCR
Morphology	passed	unaltered to reference
LOD	passed	< 0.05 EU/ml

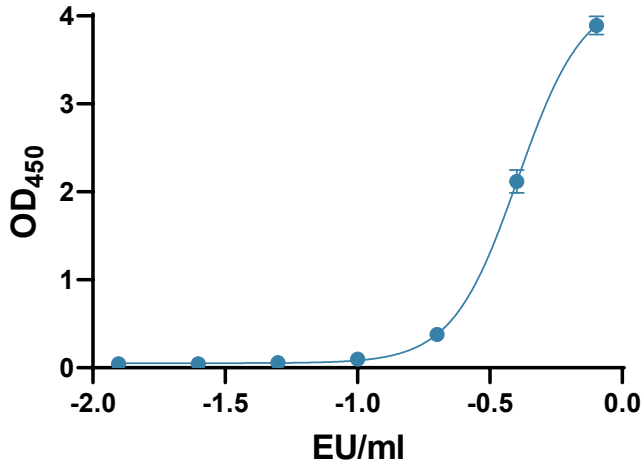
KIT CONTENT

	Cat-N°	Lot#	Storage	Quantity
Recovery Buffer A	MD163-01	91-231023ML01	-20°C	1
Assay Buffer A	MD363-06	91-240207MIL01	-20°C	1
MAT - Capture Antibody	RX509-01	91-240207MIL02	4°C	1
MAT - Detection Antibody	RX510-01	91-240207MIL03	4°C	1
MAT - Coating Buffer	RX511-01	91-240207MIL04	4°C	1
MAT - Streptavidin-HRP	RX512-01	91-240207MIL05	4°C	1
MAT - ELISA Buffer	RX513-01	91-240207MIL06	4°C	1
MAT - TMB Solution	RX514-01	91-240207MIL07	4°C	1
MAT - BRP-Standard	RX515-01	91-230113MIL01	-20°C	1
Assay Ready THP-1 macrophages	RE514	92-231122MIL01	< -140°C	1
96-well Assay Plate	ZG14-08	2020321	RT	1
96-well ELISA Plate	LM071-00	20145370	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.



MAT ASSAY



Dose response of the BRP-Standard 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.

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.

Pyrogen Assay: The assay was performed according to the 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.

