

# CERTIFICATE OF ANALYSIS

## instaCELL pyrogen detection kit

**CatN°: SF240-01**

**Lot#: PD-230127**

**Expiry Date: 13.07.2023**

### 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 $\alpha$  concentration.

### QUALITY SPECIFICATION OF THE CELLS

	Batch Quality Control	Specification Limits
Cell Count	<b>9.3E+06</b>	9.0E+06<>1.1E07
Homogeneity (cell count)	<b>98%</b>	≥ 90%
Viability (after thawing)	<b>94%</b>	≥ 90%
Debris/Cell Ratio	<b>0.8</b>	≤ 1.0
Aggregation	<b>1.3</b>	≤ 2.0
Sterility (bacteria, yeast, fungi)	<b>passed</b>	negative after 7 days
Sterility (mycoplasma)	<b>passed</b>	negative by PCR
Morphology	<b>passed</b>	unaltered to reference
LOD	<b>&lt;0.05 EU/ml</b>	< 0.05 EU/ml

### KIT CONTENT

	Cat-N°	Lot#	Storage	Quantity
Recovery Buffer A	MD163-01	91-220505NR02	-20°C	1
Assay Buffer A	MD363-06	91-211030NR01	-20°C	1
MAT - ELISA Buffer	RX513-01	91-230106ML05	4°C	1
MAT - TMB Solution	RX514-01	91-230106ML07	4°C	1
MAT - Coating Buffer	RX511-01	91-230106ML02	4°C	1
MAT - Capture Antibody	RX509-01	91-230106ML04	4°C	1
MAT - Detection Antibody	RX510-01	91-230106ML03	4°C	1
MAT - BRP-Standard	RX515-01	91-230113ML01	-20°C	1
MAT - Streptavidin-HRP	RX512-01	91-230106ML01	4°C	1
Assay Ready THP-1 macrophages	RE514	92-211125NR01	< -140°C	1
96-well Assay Plate	ZG14-08	0023821	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:

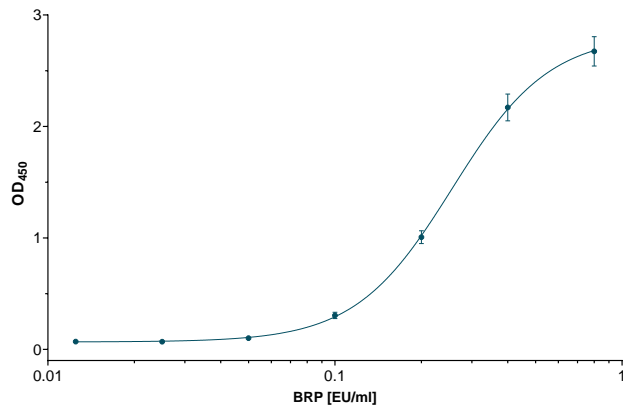
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Dose response of the BRP-Standard recommended by WHO performed according to the assay protocol.

## 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.

**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.

