CERTIFICATE OF ANALYSIS

instaCELL TNF-α Neutralization assay kit

CatN°: SF310-01
Lot#: TN-231122
Expiry Date: 16.08.2024

PRODUCT DEFINITION

Test kit to assess the neutralization potency of TNF-α inhibiting drugs 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	**3.2E+06**	1.00E+06<>5E+06
Homogenity (cell count)	**98%**	≥ 90%
Viability (after thawing)	**97%**	≥ 90%
Proliferative Capacity	**94%**	≥ 70%
Debris/Cell Ratio	**0.2**	≤ 1.0
Aggregation	**1.2**	≤ 2.0
Sterility (bacteria, yeast, fungi)	**passed**	negative after 7 days
Sterility (mycoplasma)	**passed**	negative by PCR
Morphology	**passed**	unalterd to reference
EC_{50} Infliximab Ref.	**11.6 ng/ml**	2 ng/ml and 15 ng/ml
R^2 Infliximab Ref	**0.98**	>0.97

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
Infliximab Stock Solution	RX516-01	91-220826MD01	-80°C	1
TNF-α Stock Solution	RX517-01	91-220817NR01	-80°C	1
Actinomycin D	KR115-08	220613	4°C	1
Resazurin	RX718-01	91-231018ML01	-20°C	1
Assay Ready L-929 Cells	RE772K	92-221114ML01	< -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.

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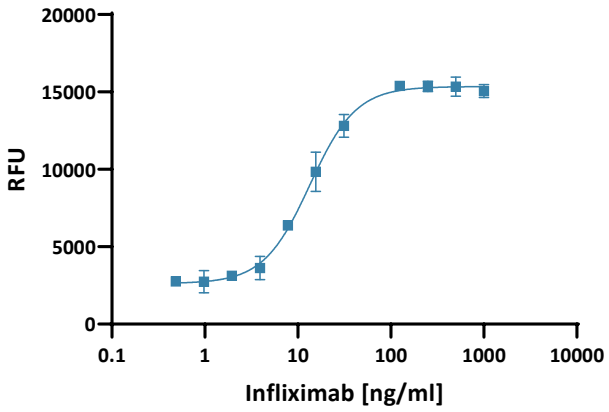
NEUTRALIZATION ASSAY



Dose-Response curve of the international Infliximab standard 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.

Neutralization 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.

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