

1321N1-huP2RX4

Assay Ready Cells

Certificate of Analysis

Lot-N°: 92-191122JP02

LOT SPECIFICATIONS

Packaging:	10 million cells / vial	Cat-N°:	AW300
Passage:	6	Cell ID:	0509
Approval Date:	27 SEP 2022	Approved by:	
Expiry Date:	23 SEP 2024		



Susan Ciura (Head of Quality Control)

QUALITY CONTROL

Parameter	Specification Limits	Batch Results
Cell Count	≥ 90 % of nominal cell count	9.70E+06 cells / vial
Homogeneity (cell count)	≥ 90 %	99 %
Viability (after thawing)	≥ 90 %	98 %
Proliferative Capacity	≥ 80 %	100 %
Aggregation	≤ 2.0	1.2
Debris Ratio	≤ 1.0	0.2
Morphology	matches reference image	passed
Sterility Testing (bacteria, yeast, fungi)	sterile after 7 days	passed
Mycoplasma Testing	negative by PCR	passed
Identity (cross species contamination)	species-specific PCR fragment	passed (human)
Identity (human STR analysis)	matches reference STR profile	n.d.

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.

