


# HEK-hu2PRX7

Assay Ready Cells

# Certificate of Analysis

Lot-N°: 92-200706VP01

## LOT SPECIFICATIONS

Packaging:	10 million cells / vial	Cat-N°:	AW270
Passage:	5	Cell ID:	0505
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	1.58E+07 cells / vial
Homogeneity (cell count)	≥ 90 %	97 %
Viability (after thawing)	≥ 90 %	90 %
Proliferative Capacity	≥ 80 %	100 %
Aggregation	≤ 2.0	1.3
Debris Ratio	≤ 1.0	0.4
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.

