

1321N1-huP2RX2

Assay Ready Cells

Certificate of Analysis

Lot-N°: 92-200528CF02

LOT SPECIFICATIONS

| | | | |
|----------------|-------------------------|--------------|-------|
| Packaging: | 10 million cells / vial | Cat-N°: | AW260 |
| Passage: | 7 | Cell ID: | 0507 |
| Approval Date: | 27 SEP 2022 | Approved by: | |
| Expiry Date: | 23 SEP 2022 | | |



Susan Ciura (Head of Quality Control)

QUALITY CONTROL

| Parameter | Specification Limits | Batch Results |
|--|-------------------------------|-----------------------|
| Cell Count | ≥ 90 % of nominal cell count | 1.09E+07 cells / vial |
| Homogeneity (cell count) | ≥ 90 % | 98 % |
| Viability (after thawing) | ≥ 90 % | 93 % |
| Proliferative Capacity | ≥ 80 % | 100 % |
| Aggregation | ≤ 2.0 | 1.3 |
| Debris Ratio | ≤ 1.0 | 0.8 |
| 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.a. |

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.

