

Risk assessment for upcyte® cells

To whom it may concern,
upcyte technologies GmbH has carried out the following risk assessment for human upcytes cells:

1) Donor: Human

Risk Group 1

2) Vector: lentivirus recombinant, replication-defective, generated using a four-plasmid system comprising of a vector, a packaging plasmid and two additional plasmids (encoding coat protein gene and Rev protein gene). The use of this method minimizes the risk of recombination towards a replication competent lentivirus, according to Clause 3.10 of the general statement of the ZKBS (central commission for biological safety) for frequently performed genetic engineering work with the underlying criteria of comparability gene transfer using retroviral vectors "Allgemeinen Stellungnahme der ZKBS zu häufig durchgeführten gentechnischen Arbeiten mit den zugrunde liegenden Kriterien der Vergleichbarkeit: Gentransfer mit Hilfe retroviraler Vektoren".

Risk Group 2

3) Recipient: Human cells from clinically normal donors tested for HBV, HCV and HIV, according to the statement of the ZKBS (central commission for biological safety) for the classification of genetic engineering work with primary cells from vertebrates. "Einstufung gentechnischer Arbeiten mit primären Zellen aus Vertebraten".

Risk Group 1

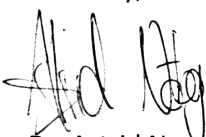
4) GMO: Human cells of risk group 1 infected with recombinant, replication-defective lentiviruses, which are not expected to contain a contamination with replication-competent retroviruses and which do not complement the replication defect, according to Clause 3.11 of the general statement of the ZKBS (central commission for biological safety) for frequently performed genetic engineering work with the underlying criteria of comparability gene transfer using retroviral vectors "Allgemeinen Stellungnahme der ZKBS zu häufig durchgeführten gentechnischen Arbeiten mit den zugrunde liegenden Kriterien der Vergleichbarkeit: Gentransfer mit Hilfe retroviraler Vektoren".

Risk Group 1

Additionally, upcyte® cells were passaged at least two times, and examined with the p24 ELISA for lentiviruses in the supernatant. The result was negative. Thus, the formation and release of replication-competent lentiviral can be excluded and the transduced cells are classified as risk group 1. There are no contraindications for the handling of the cells in a genetic engineering facility carrying out genetic engineering work at Security Level 1.

If you have any questions, do not hesitate to contact us.

Sincerely,



Dr. Astrid Noerenberg

Principal Investigator according to GenTG (German law on genetic engineering)