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Stability of infectious recombinant adeno-associated viral vector in gene delivery.

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**BACKGROUND:** The aim of this study is to provide a basis for the design of appropriate protocols for the shipping and storage of rAAV vectors for experimental laboratory studies and clinical trials.

**MATERIAL/METHODS:** rAAV stocks were generated by standard methods and then subjected to different environments. The transduction efficiency of viral vectors

both in vitro and in vivo was determined by luciferase activity and immunohistochemistry.

**RESULTS:** The virus stored at -80 degrees C remained completely stable and had high transduction efficiency. By contrast, the transduction efficiency of all other groups on 293 cells decreased continuously over time. The transduction efficiency of the -20 degrees C group remained relatively high for the first 5 days, but dropped sharply between days 5 and 7. The transduction efficiency for the 4 degrees C group dropped sharply on both days 1 and 7, and continued to decrease to 55% of maximum efficiency by the end of the first month. For both the room temperature (RT) and 37 degrees C groups, a sharp fall in efficiency was observed at day 1, and efficiency continued to decline throughout the experimental period. Data from the in vivo study also revealed that rAAV vector stored at -80 degrees C remained stable and retained its transduction efficiency.

**CONCLUSIONS:** The virus stored at -80 degrees C remained completely stable and retained high transduction efficiency. The implications of these findings provide

a basis for viral stock portioning and avoidance of freeze-thawing and storing at temperatures above -80 degrees C prior to clinical trials.

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