

PROJECT REVIEW

"Development of a Reliable Blood Test for the Detection of Gene Doping after Intramuscular Injection of Recombinant Adeno-Associated Viral Vectors"

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With the development of potent gene transfer technology, the availability for illegal gene doping is becoming more likely. To stay ahead of this eventuality, we will empower WADA/IOC with the diagnostic capability to detect genetically modified athletes (GMA). We will develop sensitive detection methods to detect illegal AAV-based gene doping from simple blood samples.

Using appropriate systems, we will design a diagnostic test and perform analytical and pre-clinical validations of the method to ensure accuracy, precision, specificity, sensitivity, and reproducibility. Eventually, a kit will be manufactured for the routine use by WADA/IOC to screen athletes for illicit gene doping-based performance enhancements.

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Results and Conclusions

In year 1, we developed sensitive and specific assays that are capable of detecting rAAV sequences in the cellular fraction of whole blood of non-human primates several months even years following Regional Intravenous or direct intramuscular administration. Presumably the assays have wide applicability to other gene transfer vector systems (lentivirus, retrovirus, Adenovirus).

In year 2, we have continued to optimize the tests and engineered a format that is easily carried out in the clinical setting. We have made two commonly used serotypes of rAAV vectors, screened the experimental animals and injected them at two different doses achieving a 55% increase in hematocrit. Vector persistence in serum, urine, whole blood and PBMCs from a single administration was determined. We determined the minimal AAV dose that can result in a low but physiological increase in hematocrit where vector sequences can be detected, and correlate the dose with the duration of detectable vector.