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Alternatives for the NIH Potency Assay for Rabies Virus Vaccines: Past and Present

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Human rabies virus vaccine potency is currently assessed using the NIH potency test, a test which measures protection against rabies virus challenge in immunized mice. While the test is well accepted as a measure of vaccine potency/efficacy, the assay has several critical problems. These include; the expense and length of the test, the use of many animals, a lethal challenge step, and a high degree of variability between assays. Vaccine manufacturers and regulatory authorities for both veterinary and human vaccines have been working for some time (decades) to develop an alternative assay to measure vaccine potency. This presentation will provide a historical perspective to alternate test development for human rabies virus vaccines and introduce considerations for an alternative potency assay based on an ELISA assay to measure rabies G glycoprotein.

