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Animal Health Institute (AHI)/Veterinary Biologics (VBS) Rabies Potency Test Working Group: Technical and Procedural Perspective

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The in vitro rabies potency assay working group, comprised of industry representatives affiliated with the Animal Health Institute (AHI), was established in ca. 2012 and, in collaboration with the Center for Veterinary Biologics-USDA, has been working to replace the NIH Rabies Mouse Potency Test with an in vitro assay. The working group has been evaluating approaches similar to those described by the EPAA (European Partnership for Alternatives to Animal Testing) and VAC2VAC and has identified two additional monoclonals that are more readily available in the US but are not being considered by either EPAA or VAC2VAC. These neutralizing rabies glycoprotein G specific monoclonal antibodies, 509-6 and 523-11 (developed by the Wistar Institute), have been shown to differentiate antigens that have been altered by temperature, deglycosylation, and low pH in an indirect EIA format. As the working group continues to characterize and optimize the proposed EIA, the group has begun to outline the procedural aspect for gaining regulatory and public confidence of an in vitro potency assay for release of rabies vaccines. This talk will focus on these key technical and regulatory aspects as they relate to veterinary vaccines.

