Rabies in vitro potency test

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3Rs implementation in veterinary vaccine batch-release testing: Current state-of-the-art and future opportunities
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**Background**

- The control of rabies inactivated vaccines for veterinary use has been implemented in Anses-Nancy since 1978 on all batches produced or imported in France before marketing.
- Anses-Nancy tests also batches of veterinary vaccines on request of international authorities.
- As a WHO CC and OMCL, we may be requested for testing new vaccine standards.
- Tests to be performed:
  - Appearance
  - Potency
SOME DATA

• Vaccines received mainly from:
  • Boehringer Hingelheim (Rabisin, Eurican LR),
  • Virbac (Rabigen mono).
• All tested using the Serological Potency Assay. This test is recognized by PAHO (since 2021).
• Challenge test (NIH test) no longer used (since 2021).
• Around 30/35 batches tested annually for OCABR.
• Around 400-600 mice used annually for SPA. With the challenge test, it would have been >4000 mice.
• The OMCL Anses-Nancy is accredited through MJA scheme according to ISO/EN/17025.
In vitro ELISA tests

- Currently in use by manufacturers to assess the amount of rabies antigen for consistent batch to batch formulation.
- Ultimate goal from a regulatory perspective: development of a single and universal G-specific ELISA as a substitution to the challenge test. Hardy achievable:
  - Slight variations of rabies virus strains,
  - Monoclonal antibody specificities,
  - Adjuvant differences and technical issues to liberate antigen from adjuvant.

Source: NIVEATM and IABS report, 2019; Gibert et al., 2013; Schifferlers et al., 2014; Sigoillot-Claude et al., 2015; Stokes et al., 2012.
Perspectives of *in vitro* ELISA tests at Anses-Nancy

- No unique ELISA test for all rabies inactivated vaccines.
- Need to implement different ELISAs depending on the vaccines under test.
- Achievable for vaccines from Boehringer Ingelheim.
- Requirements:
  - Transfer and validation of the ELISAs procedures,
  - Time/Ressources,
  - Laboratory equipment,
  - Accreditation.

Source: VBRN Annual Meeting, 2022