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VALIDATION OF AN INDIRECT ELISA FOR THE DETECTION OF ANTIBODIES AGAINST EQUINE INFECTIOUS ANEMIA VIRUS (EIAV) IN EQUINE SERA USING GAG AND ENV RECOMBINANT ANTIGEN

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Purpose

Validation of an indirect ELISA using Gag and Env recombinant antigen of EIAV is presented.

Methods

Validation performed according to WOAH guidelines.

Analytical specificity

1. Selectivity: evaluated by examining positive and negative sera using a modified wash.
2. Exclusivity: evaluated examining sera positive for other Lentivirus and other equine viral diseases.

Analytical sensitivity

3. Limit of detectability (LOD) of ELISA compared with AGID.
4. Sera of infected horses at different d.p.i., tested with 6 ELISA available in Italy and AGID.

Repeatability

5. Coefficient of variation (CV) of 2 sets of 30 negative serum replicas.

Reproducibility

6. Qualitative: K of Cohen calculated on results of an interlaboratory test.
7. Quantitative: Standard deviation (S_R) of 7 sessions of 30 negative serum replicas.
8. *Diagnostic performances*
   1095 sera analysed with ELISA and AGID as gold standard. Sensitivity, specificity, positive and negative predictive values were calculate

Results

1. Modified ELISA did not correctly recognise sera.
2. All sera classified as negative.
3. ELISA LOD: 1,86 Log_{10} higher than AGID.
4. This ELISA recognised as positive 9 sera at 21 d.p.i., 2/6 kits 1 serum, 3/6 kits and AGID none.
5. CV less than 20% (2.6-4.3%).
6. K value: 0.976.
7. S_R : 0.039.
8. Sensitivity: 100%; specificity: 98.8%; positive and negative predictive value: 91.18%; 100%, respectively.

Conclusions

Considering all characteristics evaluated, especially in terms of repeatability, reproducibility, diagnostic sensitivity and precocity, the test is highly suitable for screening purposes.

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