

Technical report EIAV sera 11.2014.00

Eradikit® EIAV kit

Analyses on problematic sera

In3diagnostic s.r.l.

Sede legale: via B. Drovetti 4, 10138, Torino, Italia - Sede operativa: via L. da Vinci 44, 10095, Grugliasco (TO) - Italia

CF/P.IVA 10842130014 - REA: TO-1166395

Tel 0039 0116709200 - Fax 0039 0116709196 - info@in3diagnostic.com

www.in3diagnostic.com

With the collaboration of dr. Mandola (*Istituto Zooprofilattico di Piemonte Liguria e Valle d'Aosta, IZSPLV, Italy*) we tested a total of 105 problematic sera. All samples were negative to AGID test and included hemolytic and lipemic sera.

We tested those sera in order to evaluate if sera characteristics can influence the test's specificity, increasing the number of false positive results

The test was conducted following the Protocol #1, validated by the Italian Reference Laboratory for Equine Infectious Anemia

The AGID Weak Positive Control (WC, lot 01/89/4) as well as the AGID Negative Control (NC) provided by the IZSPLV were included in the test evaluation

Results, expressed as the percentage of optical density compared to the positive control (%OD), are reported in Figure 1.

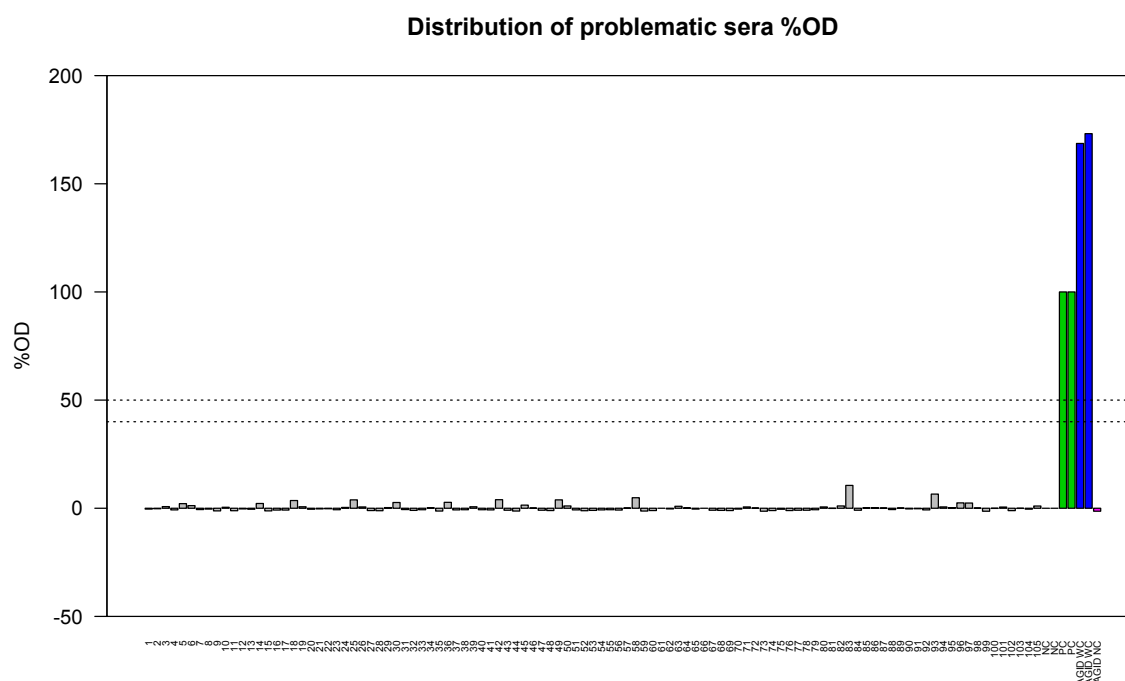


Figure 1

Fig.1 Reactivity's percentage of tested sera. Eradikit EIAV Positive Control is represented by green bars; IZSPLV WC is represented by blue bars; Negative Controls are reported as red bars (Eradikit Negative Control is not visible because is equal to zero). Horizontal dotted lines represent positivity (50%) or doubtful (40%) cutoffs.

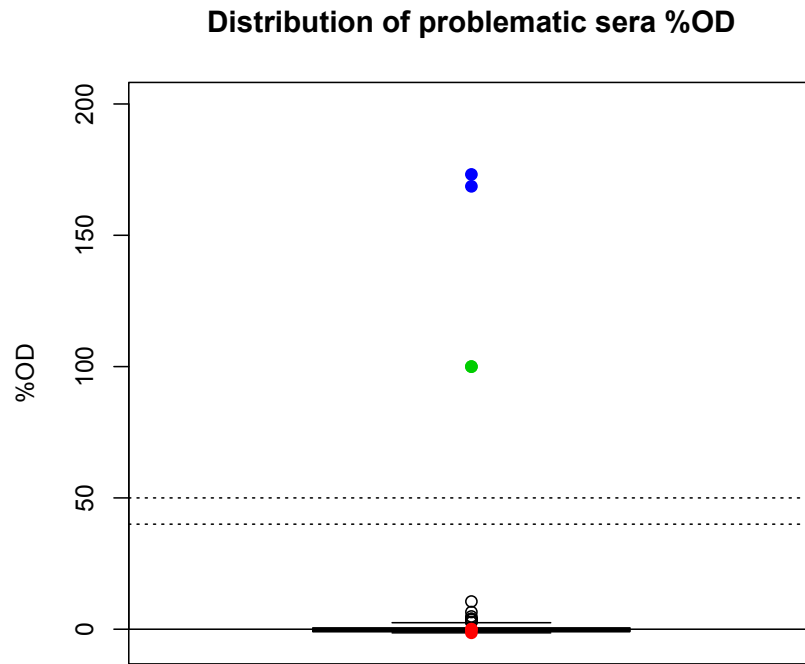


Figure 2

fig.2 Distribution on %OD of tested sera. Eradikit EIAV Positive Control is represented by green dots; IZSPLV WC is represented by blue dots; Negative Controls are reported as red dots

In order to verify if serum quality can influence the test performances, we created artificial positive samples by serially diluting the Weak AGID Positive Control in 7 different negative problematic sera as follow:

- 2 highly lipemic sera (rows A e B in fig. 3)
- 2 slightly lipemic sera (rows C e D)
- 2 highly hemolytic sera (rows E e F)
- 1 normal negative serum (Eradikit NC, row G)

Two-fold dilutions were prepared from 1:2 to 2:16. Each dilution was tested according the Protocol #1

Results are reported in fig.4 and expressed as %OD.

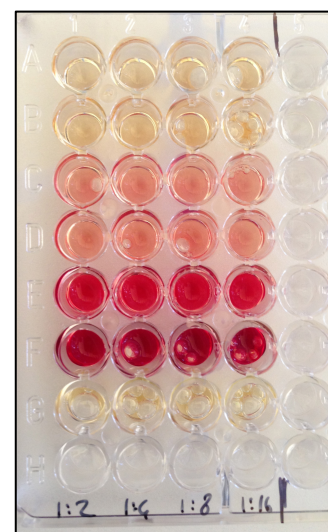


Figure 3

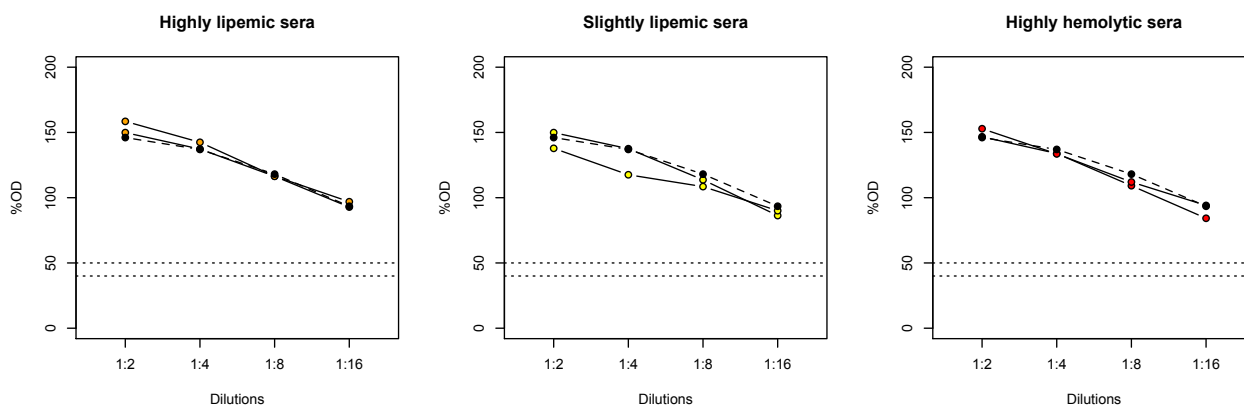


Figure 4

In each panel, reactivity of the positive control diluted into problematic sera is compared to the reactivity of the same sample diluted into a good-quality negative serum (black dots and dashed lines). Horizontal dotted lines represent positivity (50%) or doubtful (40%) cutoffs.

No evidence of inhibition caused by the serum poor quality are present, considering the absolute overlap between problematic and normal serum reactivity.

Conclusions

Performed tests indicated that neither lipemic nor hemolytic sera can influence Eradikit EIAV test performances, in terms of both specificity and sensitivity.