Abstract

Clinical evaluation of the DVM Rapid Test Equine IgG Turbidimetric Immunoassay (TIA) for use in monitoring passive transfer of immunoglobulins in foals.

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Objective: To determine the predictive ability of the Value Diagnostics Equine Serum IgG TIA test kits in comparison with the SNAP® Foal IgG Test.

Samples: A total of 78 plasma or serum samples obtained from 51 foals.

Procedure: Serum or Plasma (EDTA or Heparin) samples were obtained from foals, at defined times in the first 48 hours post partum. The IgG concentrations were determined using both the SNAP® Foal IgG Test and the Value Diagnostics DVM Rapid Test turbidimetric immunoassay (TIA) by the laboratory staff at the New Bolton Center. Any foals having serum IgG concentrations below 800 mg/dl whether pre or post treatment were re-sampled and re-tested by both methods. All Samples were frozen, transferred to Integrity Biologics (IBI) for confirmatory testing using the Value Diagnostics TIA test kits and a Pointe-180 analyzer calibrated with USDA Secondary Reference Standards. Sensitivity, specificity, accuracy and predictive value were calculated on the average of triplicate IgG concentrations determined by the TIA methodology performed by Integrity Biologics. For predictive value theory all test results were assigned a value of Positive FPT = < 800mg/dl and Negative FPT = >800mg/dl. Statistical comparison of values obtained with the semi-quantitative SNAP® Foal IgG Test and the quantitative TIA test were based on assigning a numerical value of 1 = <400 mg/dl, 2 = 400mg/dl - 800mg/dl and 3 = >800mg/dl.

Results: Of the 78 samples tested, 17 samples showed discrepancies between the two methods when assayed by the laboratory staff at New Bolton Center. Of these 17 samples, 11 yielded results of >800mg/dl by the SNAP® Foal IgG Test and values between 400 and 800mg/dl by the TIA methodology performed by New Bolton Center. 9 of the 11 samples yielded comparable results of 400mg/dl - 800mg/dl by the TIA methodology when performed by IBI and 2 samples tested slightly below 800mg/dl at New Bolton and slightly above 800mg/dl at IBI. 3 samples yielded results of 400mg/dl - 800mg/dl by the SNAP® Foal IgG test and <400mg/dl by the TIA test at both labs. The final three samples yielded results of <400mg/dl by the SNAP® Foal IgG Test and values between 400 - 800mg/dl by the TIA methodology at both labs.

The sensitivity, specificity and accuracy of the DVM Rapid Test TIA for Equine plasma IgG was 100%, 94.4% and 97.4% respectively. The Positive and Negative Predictive Values were 95.5% and 100%. The correlation coefficient between the TIA and SNAP® Foal IgG test as performed by New Bolton Center was $r^2 = .7820$. The inter-laboratory correlation coefficient for the TIA methodologies was $r^2 = .9721$.

Table 1 - Sensitivity (Se), specificity (Sp), accuracy, positive-predictive value (PPV) and negative-predictive value (NPV) for the TIA and SNAP® Foal IgG Test used to measure IgG concentrations in 78 serum or plasma obtained from newborn foals.

Method	**(TP)***	**(FP)**	**(FN)**	**(TN)**	Se %	Sp %	Accuracy %	PPV%	NPV%
TIA	42	2	0	34	100	94.4	97.4	95.5	100
Snap Foal	33	0	9	36	78.6	100	88.5	100	80.0

*TP = True Positive, FP = False Positive, TN = True Negative , FN = False Negative

Conclusions and Clinical Relevance: The purpose of this study was to have a veterinary clinical lab independently evaluate the performance of the DVM Rapid Test TIA for Equine plasma IgG test in direct comparison to the SNAP® Foal IgG Test. The New Bolton Center was chosen for this study because they have an above average number of positive FPT cases. The results of this study show that the Value Diagnostics DVM Rapid Test TIA had much higher sensitivity, accuracy and Negative Predictive Values in comparison to the SNAP® Foal IgG test. Conversely the SNAP® Foal IgG test demonstrated slightly better Specificity and Positive Predictive Values in determining the concentration of IgG in serum and plasma samples from newborn foals. The differences in the later were based on two borderline cases that would be judge to be near normal values and not require treatment. This is an important distinction , in that, the TIA method is based on an accurate instrument reading that translates into a quantitative value, compared with a methodology that is based on an individual's empirical interpretation that translates into semi-quantitative results that may limit the clinical options. This is illustrated most prominently by the discrepancies in IgG values of a number of Positive FPT. Overall the data suggest that the TIA methodology is better at rapid identification of low plasma IgG levels and the severity of the IgG deficit, which is critical both in determining the need for IgG supplementation and the level of treatment necessary.