**抗水禽雷氏桿菌症卵黃抗體製劑**

**動物攻毒效力試驗替代方法之研究**

製劑研究組

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**摘要**

有關疫苗和抗體製劑等動物生物藥品效力檢驗試驗，目前多以免疫標的動物後攻毒之方式進行評估，此法可直接且精確的顯示動物免疫反應結果。本研究為小鴨接種抗第1和2血清型水禽雷氏桿菌雙價卵黃抗體製劑後攻毒之效力試驗成績，與其血清中卵黃抗體力價(ELISA)數據進行彙整分析，找出實際保護力與卵黃抗體力價兩者之線性關係，以達成使用檢測抗體力價(in vitro)取代攻毒動物(in vivo)方式評估本雙價卵黃抗體製劑之效力，並可供未來國家檢驗標準制定之參考。此外，後續開發抗其他血清型RA菌抗體製劑時，對無法以攻毒方式評估效力者，改為檢測抗體力價進行評估，最終朝實驗動物3Rs替代減量原則之目標邁進。

***關鍵字：****水禽雷氏桿菌、卵黃抗體、效力評估、攻毒替代*

**Study on Substitution Method for Efficacy Evaluation of Egg Yolk Antibody against *Riemerella anatipestifer* Infection**

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**Abstract**

For the efficacy test of animal biologics, most vaccines and antibody biologics are evaluated by challenging target animals, which is a more direct and accurate manifestation of immune response in animals. The study aims to find the correlation between challenging protections and sera IgY titers in ducks in order to replace the current challenging ducks (in vivo) method with sera IgY titers detection (in vitro) method for efficacy evaluation of bivalent egg yolk antibody against *Riemerella anatipestifer* infection. In addition, for those anti-RA IgY products failing to evaluate the efficacy with challenge animals, the detection of sera IgY titers may serve as an alternative for efficacy assessment. The 3Rs principles goal could be achieve gradually by reduction in the number of laboratory animals used.

***Keywords***: *Riemerella anatipestifer*, egg yolk antibody, efficacy evaluation, substitution for challenge