

EVALUATION OF THE TRINITY BIOTECH KIT MODIFIED FOR THE DETERMINATION OF RUBELLA IMMUNOGLOBULIN G AVIDITY TESTING, COMPARED TO EUROIMMUN AVIDITY TEST

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BACKGROUND: Rubella infection during pregnancy poses a significant risk of congenital rubella syndrome (CRS), particularly when infection occurs during early gestation. In routine serology, cases may present with both IgM and IgG positivity, making it difficult to distinguish between recent primary infection and past exposure or reinfection. This distinction is critical, as recent infection is associated with a significantly higher risk of CRS. IgG avidity testing addresses this limitation by differentiating low-avidity antibodies (recent infection) from high-avidity antibodies (past infection).

OBJECTIVES: This study aimed to evaluate a modified Trinity Biotech IgG avidity assay as a cost-effective alternative to the Euroimmun assay (gold standard).

METHODS: A total of 29 stored serum samples from antenatal patients previously tested for rubella serology were analyzed. Samples were tested using the Euroimmun avidity assay and a modified Trinity Biotech ELISA incorporating a urea-based chaotropic step. Avidity indices were categorized as low, equivocal, or high. The agreement was assessed using correlation analysis and Cohen's Kappa coefficient.

RESULTS: The Euroimmun assay classified 93.1% (27/29) of samples as high avidity, while the modified Trinity assay classified 79.3% (23/29) as equivocal. Overall agreement was low (13.8%), with a weak correlation ($r = 0.25$) and poor Kappa agreement (-0.40). Adjustment of Trinity cut-offs improved classification distribution.

CONCLUSION: The modified Trinity assay showed limited agreement with the Euroimmun assay. Standardization of assay conditions and cut-off optimization are required. However, the assay demonstrates potential as a cost-effective alternative for improving rubella diagnosis and CRS risk assessment.