# Abstract Submission

*Transfusion transmitted infections*

*Screening strategies for TTI*

ISBTBasel-851

## EVALUATING AN AUTOMATED CMV SCREENING ASSAY AT THE IBTS- A CHALLENGING PROCESS FOR BLOOD SCREENING LABORATORIES

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**Background:** Cytomegalovirus (CMV) sero-prevalence in Ireland is lower than that which is reported in many other European countries. A study of 1047 pregnant women in 2002 found that 30.4% of Irish women were CMV seropositive in comparison to 56% from Western Europe and 92% Eastern Europe and 97% from Africa. An internal study carried out by the Irish Blood Transfusion Service (IBTS) in 2010 indicated the rate of CMV seropositivity in Irish Blood donors was 21.97%. Therefore a significant proportion of the Irish donor and recipient population are susceptible to primary CMV. This is of particular concern for patients for certain at-risk groups such as very-low birthweight CMV seronegative neonates, CMV seronegative patients undergoing transplantation and other CMV seronegative immuocompromised patients. This results in a demand for the provision of CMV sero-negative blood components. In 2018 the IBTS evaluated the Abbott Alinity s CMV IgG assay as a replacement for the CMV Mastazyme EIA (Total AB EIA).

**Aims:** To assess the performance of the Abbott Alinity s CMV IgG screening assay in comparison to the CMV Mastazyme EIA (Total AB EIA).

**Methods:** Diagnostic sensitivity was determined by testing 48 confirmed CMV IgG positive donors from an external laboratory. Sensitivity was assessed using three seroconversion panels (n=54). Analytical sensitivity was calculated using linear regression analysis of the WHO first international standard for anti-CMV IgG. Diagnostic specificity was determined by testing 6127 donors. Further evaluation of discordant results was carried out using the Architect anti-CMV IgG and IgM assays and VIDAS anti-CMV IgG and IgM assays.

**Results:** The diagnostic sensitivity of the Alinity s anti-CMV IgG assay was determined to be 100%. The seroconversion sensitivity reported 42 out of 54 samples reactive. The analytical sensitivity of the Alinity s CMV IgG assay was determined to be 1.12 IU/ml. The validation reported 65 discordant results from 6127 donor samples tested with both the Alinity s CMV IgG assay and the current Mastazyme total assay. 60 discordant results were observed (Alinity s anti-CMV IgG positive/Mastazyme total negative). Further testing of these samples classified 27 discordant results as positive, 12 as negative and 21 as indeterminate. 5 discordant results were observed (Alinity s anti-CMV IgG negative/Mastazyme total positive). Further testing classified these samples as negative. Overall the diagnostic specificity was determined to be 99.80%.

**Summary / Conclusions:** Both the seroconversion and analytical sensitivities are comparable between the Alinity s CMV IgG assay, the CMV Mastazyme Total AB assay, the Architect CMV IgG assay and the Vidas IgG assay. The slight variations can be attributed to the individual assay cut-off definitions, which can vary greatly between CMV assays. It must be noted that the determination of the diagnostic specificity (99.80%) does not include indeterminate discordant results. Further testing will be carried out to try to characterize all discordant samples in collaboration with Abbott. This evaluation did not identify any donors with isolated confirmed CMV IgM antibodies in a pool of 6127 donors. Based on this evaluation the Abbott Alinity s CMV IgG assay is a suitable replacement to the Mastazyme total AB assay for blood donor screening.