P1387
Poster Session V
Molecular and non-molecular diagnostics of viruses

AN EVALUATION OF NINE RUBELLA IGG ASSAYS HIGHLIGHTS MANY DISCREPANCIES IN THE INTERPRETATION OF THE RESULTS

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Background/Objective

Immunity to Rubella virus is commonly determined by measuring specific immunoglobulin G (RV-IgG). However, RV-IgG results/interpretation may be very different and even discordant, depending on the assay used, even though results are expressed in IU/m and all immunoassays calibrated with the same international standard (RUB-1-94). Discrepancies have an impact on diagnosis (confusing results resulting in difficult clinical management of pregnant women, and probably many useless re-vaccinations in a context of suspicious attitude of general population towards vaccination). It also has an impact on seroprevalence studies (the results of which depend on the assays used) which is particularly important in the frame of the elimination goal for Rubella. To provide objective data emphasizing the discordance between different commercial diagnostic assays, a working group (Rubella Standardization Committee) undertook a comparative evaluation of 9 commercial RV-IgG assays currently available in Europe.

Study design

A panel of 325 pretested negative RV-IgG samples (results below the cut-off value of the assay used) collected during pregnancy were tested with 9 assays: Immuno-blot (Mikrogen), Dxi (Beckman-Coulter), Architect (Abbott), Vidas (bioMerieux), Enzygnost (Siemens), LXL (Diasorin), Cobas 6000 (Roche Diagnostic), Centaur (Siemens) and Serion according to the manufacturer's instructions. Left-over samples chosen for this study came from France, Germany and Italy, and testing was performed by the French National Reference Laboratory and by the Institute for Virology in Freiburg (Germany).

Results

Only 129 out of the 325 samples (39.7%) were found RV-IgG negative with all assays. On the opposite, 59 % samples were found positive with the immuno-blot, but only 3%, 7%, 10% and 20% with the Architect, the Serion, the LXL, and the Vidas assays respectively, and around 35% with the Enzygnost, the Centaur and the Cobas 6000 assays. Moreover, up to a factor 10 of the RV-IgG titers was observed for some samples depending on the assay performed.

Conclusion/Discussion

Our results indicate that at least half women considered seronegative for Rubella are in fact immunized. Moreover, sensitivity differs greatly between assays and the 10 IU/mL usual cut-off seems no longer appropriate to determine the immune status to Rubella. The thresholds currently recommended by manufacturers certainly need to be re-evaluated in order to harmonize the interpretation of RV-IgG results.