CORRESPONDENCE

Automated rubella antibody screening: a cautionary tale

In the UK, rubella vaccination is offered to seronegative adult women, identified by rubella antibody screening and, as measles, mumps and rubella vaccine (MMR), to children in the second year of life [1]. This policy has resulted in a decline in the number of cases of rubella in pregnancy and congenitally acquired rubella. Before the introduction of rubella vaccination there were >100 infants born with congenital rubella each year, compared with 4–5 per year in 1991–1995. Many of the women who acquired rubella in pregnancy in the 1990s were born outside the UK and probably were never offered rubella vaccination [2]. Uptake of MMR vaccine among children has declined since 1995, partly due to anxiety about vaccine safety caused by adverse publicity. An increase in rubella incidence is now anticipated with consequent exposure of susceptible pregnant women; therefore it is important that susceptible women of child-bearing age are identified by rubella antibody screening.

Many laboratories use automated assays for rubella antibody screening. In our laboratory 12 000 sera are tested annually for rubella antibodies with a fully automated microparticle enzyme-immunoassay (MEIA; Abbott Diagnostics). We use a cut-off of 12 IU/ml, although 10 IU/ml is recommended by the manufacturers. According to the recommendation of a PHLS Working Party [3] we re-test sera with undetectable (<5 IU/ml) or a low level (5–12 IU/ml) of antibodies by latex agglutination (LA; Orion Diagnostica). There is normally good correlation between the LA and MEIA, but during the last few months occasional sera with antibody concentrations of 7–13 IU/ml on MEIA were negative on LA and confirmed as negative by LA and single radial haemolysis elsewhere.

As these findings caused some concern, we retrospectively examined our rubella antibody screening

results for the previous 6 months, to find that 315 (5.7%) of the 5446 sera tested gave antibody concentrations of <12 IU/ml by MEIA. Concordant results were obtained for 87% of these by LA, but of 53 sera with results of 10–12 IU/ml, three were negative and six gave weak positive results on LA. Thus, if we had been using 10 IU/ml as cut-off, as recommended by the manufacturer, we would have reported false positive results, albeit rarely – 9 (0.17%) of 5446 sera. To avoid false positive results and the risk of susceptible women not being offered vaccination [4], we further increased the cut-off of our MEIA screening assay to 15 IU/ml.

This problem highlights the need to retain laboratory staff with virological experience and expertise to interpret results and identify potential problems. It is important to remain vigilant and not to rely uncritically on automated assays, which are used increasingly for large-scale screening.

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