

Qualitative and quantitative tests are acceptable for this purpose (16). Assay sensitivity ranged from 78.6 to 92.4% in the low antibody concentration range. None of the commercial immunoassays (Elecsys, Enzygnost, Vidas, AxSYM, Liaison, and Architect) reported false-positive results using the manufacturers' cutoffs or a cutoff of 10 IU/ml. Diagnosis of acute rubella virus infection or reinfection can be made by detection of rubella virus-specific IgM and the detection of a clinically relevant rise in the rubella virus-specific IgG concentration (4, 17). With regard to qualitative results, i.e., positive (previous exposure to rubella) or negative (no previous exposure), there was a very high level of agreement between the HI test and Enzygnost and Elecsys assays over the whole set of 1,090 unselected samples from routine testing. Hence, quantitative IgG tests are essential for a correct diagnosis and the adequate management of pregnant women who may have been exposed to rubella virus. The majority of assays also employ an equivocal or gray zone.