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Method Change - anti Rubella IgG

Explanation of Change:

Testing for rubella IgG antibody will be changed from the Abbott AxSYM to the Beckman Access starting on May 28, 2003 due to a substantially long period of reagent back order from Abbott. Because of the differences in methods and the cutoff values by different manufacturers, the number of positives determined by the Beckman method will be decreased slightly.

Background:

The detection of specific rubella antibodies is of great interest due to the teratogenic risk related to a rubella primary infection at the beginning of pregnancy. Infections in utero, particularly during first four months of pregnancy, can lead to congenital defects such as deafness, cardiac problems, cataracts or glaucoma, and sometimes fetal death. Demonstration of rubella IgG antibody in a pregnant woman prior to conception provides assurance of fetal protection from possible rubella viral infection during pregnancy. Vaccination efficiency is demonstrated by detection of rubella IgG antibody in serum following immunization. Appearance or significant rise of specific IgG concentration in two serum samples collected at least two weeks apart is indicative of rubella infection, even when the typical symptoms may not be present.

Method:

Beckman Access Rubella IgG assay is a chemiluminescent immunoassay for the qualitative and quantitative determination of IgG antibodies to the rubella virus in human serum.

Reference Intervals:

Reference interval will be changed accordingly:

Current: Positive: >=10 IU/mL Borderline: 5-9.9 IU/mL Negative: <5 IU/mL

New: Positive: >=15 IU/mL Equivocal: 10-14.9 IU/mL Negative: <10 IU/mL

Supportive Data:

Beckman Access Rubella assay was compared with the Abbott AxSYM Rubella assay using 109 patient specimens. Values from Access are about 30% higher than that from AxSYM.

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