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SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary for The Murex Rub-~~α~~ Test

SAFETY AND EFFECTIVENESS

The Murex Rub-~~α~~ test is a rapid latex agglutination test for the qualitative and semi-quantitative determination of rubella antibodies in serum. The rubella virus used to sensitize the Latex Reagent is inactivated and disrupted before use. Sera used in the preparation of controls are tested with FDA approved tests for hepatitis B virus surface antigen (Hbsag) and antibodies to HIV and hepatitis C virus (HCV). Only units that are non-reactive for Hbsag and antibodies to HIV and HCV are selected. When used in accordance with the principles of Good Laboratory Practices, good standards of occupational hygiene and the instructions in the Package Insert, the reagents supplied with the test kit are not considered to present a hazard to health.

The Latex Reagent and serum controls contain 0.1% sodium azide as a preservative. Lead and copper in laboratory plumbing can react with sodium azide to produce lead and copper azide which can explode on percussion. Murex recommends that drains are flushed thoroughly with water after disposing of reagents containing sodium azide.

The Murex Rub-~~α~~ test showed an equivalent performance in comparative studies with test kits distributed by Becton Dickinson and Orion Diagnostics. Any differences between the Murex Rub-~~α~~ test and either Rubascan or Rubalex do not compromise the safety and efficacy of the product nor do they represent a potential unreasonable risk of illness or injury.