

K954687

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

1. General Information

Device Classification Name: Rubella Virus Serological Reagents

Device Trade Name: ACCESS® Rubella IgG Reagents

Applicant's Name and Address: Sanofi Diagnostics Pasteur, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

2. Predicate Device Abbott IMx Rubella IgG
Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064

3. Device Description

The ACCESS® Rubella IgG assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative and quantitative determination of IgG antibodies to the Rubella virus in human serum, using the ACCESS® Immunoassay System. The ACCESS® Rubella IgG assay aids in the diagnosis of Rubella infection and the determination of immunity.

4. Summary of Studies

In clinical studies, the ACCESS® Rubella IgG was compared to HAI on 784 patient serum samples. The relative sensitivity and specificity were 98% and 99%, respectively.

A comparison to the Abbott IMx Rubella IgG was done on 670 patient serum samples. The concordance was 90%.

Representative data for within run, within site and total precision are 15%, 15% and 16% for the QC1 negative control, 6%, 6% and 6% for the QC2 low reactive control, and 9%, 11% and 12% for a high positive sample.

5. Conclusion

The Sanofi Diagnostics Pasteur ACCESS Rubella IgG is substantially equivalent to a standard laboratory reference method (HAI) and to another kit currently in commercial distribution for the determination of IgG antibodies to Rubella in human serum samples.