

K952721

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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	<b>RUBAscan</b> <sup>®</sup> Card Test
Common Name/Description:	Latex agglutination for Rubella antibodies
Classification Name:	Latex agglutination assay, Rubella

PREDICATE DEVICE:

K832228; **RUBAscan**<sup>®</sup> Card Test

DEVICE DESCRIPTION:

**INTENDED USE:** The **RUBAscan**<sup>®</sup> Card Test is a passive latex agglutination test for the detection and/or quantitation of rubella antibodies in human serum. The test is configured to give qualitative results by testing specimens either undiluted or diluted 1:10 to yield two sensitivity levels for detecting rubella antibodies. The choice of protocol used may be based upon judgments concerning the significance of immune status given by antibody levels in protecting the individual from primary rubella infection.

The **RUBAscan**<sup>®</sup> Card Test can also be used to give quantitative results when used to test serial dilutions of the specimen. With properly selected paired specimens, the test can determine recent or active infection.

**KIT DESCRIPTION:** The **RUBAscan**<sup>®</sup> Card Test is based upon the well established principles of passive latex agglutination. Latex is sensitized according to a patented process using solubilized rubella virus antigens from disrupted virions. This latex reagent, when mixed with serum containing rubella antibodies on a card surface, will agglutinate, forming visible clumps. In the absence of antibody, or if the concentration is insufficient to react, the latex will remain smooth and evenly dispersed.

A single specimen can be used to obtain a qualitative judgment about its antibody content. Analysis of dilutions of the specimen can give quantitative results.

#### PERFORMANCE DATA:

**Clinical Correlation:** The following studies were conducted to enable the addition of a quantitative sensitivity claim of 10 IU/mL at the 1:10 screening dilution. The NCCLS guideline I/LA6-T was used as a guideline for performing the testing.

- Internal testing was conducted to validate that the **RUBAscan®** Card Test dilution of 1:10 is equivalent to the 10 IU/mL cut-off.

**Conclusion:** The **RUBAscan®** Card Test met the acceptance criteria ( $\geq 95\%$  as suggested by the NCCLS guidelines) for sensitivity and specificity of the in-house testing at the dilution of 1:10 when a commercially available EIA was used as the reference and a commercially available latex assay was used to resolve nonconcordant results.

- Two external studies were conducted to validate that the screening dilution of the **RUBAscan®** Card Test in clinical laboratorians' hands was equivalent to the 10 IU/mL immune status cut-off as defined by the commercially available EIA.

**Conclusion:** The **RUBAscan®** Card Test resolved sensitivity and specificity met the 95% confidence intervals for the observed sensitivity and specificity including 95% at the two sites.

- A CDC evaluation panel was tested internally using a 1:10 dilution.

**Conclusion:** The **RUBAscan®** Card Test identified all 100 samples correctly.

#### **Reproducibility:**

- Two external studies were conducted to validate dilution reproducibility at the 10 IU/mL cut-off.

**Conclusion:** Reproducibility of the **RUBAscan®** Card Test was acceptable.