

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k031490

B. Analyte:

Rubella antibodies

C. Type of Test:

Latex particle agglutination test

D. Applicant:

Immunostics, Inc.

E. Proprietary and Established Names:

Rubellacol

F. Regulatory Information:

1. Regulation section:
21 CFR 866.3510, Rubella Virus, Serological Reagents
2. Classification:
Class II
3. Product Code:
LQN, Latex Agglutination Assay, Rubella
4. Panel:
Microbiology (83)

G. Intended Use:

1. Intended use(s):
Rubellacol is a color enhanced rapid latex agglutination slide test for the qualitative and semi-quantitative detection of rubella virus antibodies in serum. Rubellacol slide test is a rapid latex particle agglutination test aiding in the diagnosis of recent or active rubella infection and the determination of immune status. The assay's performance characteristics have not been established for prenatal or newborn testing.
2. Indication(s) for use:
The Rubellacol test is to be used as an aid in the detection of anti-rubella virus antibodies in serum. This test is "For professional Use Only."
3. Special condition for use statement(s):
4. Special instrument Requirements:

H. Device Description:

The Rubellacol reagent is a suspension of deeply colored polystyrene latex particles of uniform size coated with a soluble purified K2S antigen extract prepared from Rubella HPV-77 virus grown in African Green Monkey Kidney Vero cell line.

I. Substantial Equivalence Information:

1. Predicate device name(s):

Wampole Impact Rubella Slide Test

2. Predicate K number(s):
k844435
3. Comparison with predicate:

| Similarities | | |
|--------------|----------------------------------|----------------------------------|
| Item | Device | Predicate |
| 1. Material | Polystyrene latex particles | Polystyrene latex particles |
| 2. antigen | Disrupted virus | Disrupted virus |
| 3. procedure | Qualitative and semiquantitative | Qualitative and semiquantitative |
| Differences | | |
| Item | Device | Predicate |
| 1. Material | Color change latex particles | White latex particles |
| 2. dilution | Initial serum dilution at 1:10 | Initial serum dilution at 1:8 |

J. Standard/Guidance Document Referenced (if applicable):**K. Test Principle:**

The latex particles are matched with compatible dyes in the suspension buffer which results in a color-enhanced visual observation of the antigen-antibody reaction.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Reproducibility of the end point is greater than 92%.

b. *Linearity/assay reportable range:*

No prozone effect up to 1600 IU/ml.

c. *Traceability (controls, calibrators, or method):*

WHO Standard

d. *Detection limit:*e. *Analytical specificity:*

No cross reactivity study was performed. A limitation is placed stating that the users should establish their own cross reactivity data.

f. *Assay cut-off:*

10 IU/ml

2. Comparison studies:a. *Method comparison with predicate device:***Study #1:**

A comparison study was conducted at Immunostics Inc. comparing 545 human serum specimens containing known Rubella positive, borderline and negative samples retrospectively collected. The demographic and geographic distribution was not

specified but were collected from donor centers around the USA. These samples were assayed employing the Rubellacol slide test and a commercially available latex agglutination test.

Positive Agreement: 99.4% (471/474)

Negative Agreement: 93% (66/71)

Positive Agreement: 98.5% (537/545)

Study #2:

A second comparison study was conducted at a private research and product development facility in Mid-Atlantic region of the United States. 200 human serum specimens containing known Rubella positive, borderline and negative samples retrospectively collected were tested. The demographic and geographic distribution was not specified but were collected from donor centers around the USA. These samples were assayed employing the Rubellacol slide test and a commercially available latex agglutination test.

Positive Agreement: 100% (187/187)

Negative Agreement: 84.6% (11/13)

Total Agreement: 99% (198/200)

Study #3:

A third comparison study was conducted at a large metropolitan hospital in New England comparing 200 human serum specimens containing unknown Rubella titers. The samples were prospectively collected from the hospital's research sample bank. The demographic distribution was not specified but the samples were from hospital patients from the New England area. These samples were assayed employing the Rubellacol slide test and a commercially available latex agglutination (LA) test.

Positive Agreement: 99.4% (178/179)

Negative Agreement: 85.7% (18/21)

Total Agreement: 98% (196/200)

CDC Panel

The panel (50 specimens in duplicate) consisted of 82% positive and 18% negative samples. The Rubellacol test demonstrated 100% agreement with the positive specimens and 100% agreement with negative specimens.

b. Matrix comparison:

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
5. Expected values/Reference range:

M. Conclusion:

The Performance characteristics reported here for the device indicate that it is comparable to the other such test kits currently in the market.