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K963613

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## 510 (k) Summary of Safety and Effectiveness

*This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.*

**Name:** Diagnostic Products Corporation  
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**Contact Person:** Edward M. Levine, Ph.D.  
Director of Clinical Affairs

**Date of Preparation:** January 20, 1997

**Device Name:**  
**Trade:** IMMULITE® Rubella IgG  
**Catalog Number:** LKRBZ (50 tests); LKRB2 (200 tests)  
**Common:** Reagent system for the determination of rubella IgG antibodies in human serum.

**Classification:** Class III device (866.3510)

**Manufacturer:** Diagnostic Products Corporation (DPC)  
5700 West 96th Street  
Los Angeles, California 90045

**Establishment Registration #:** #2017183

**Substantially Equivalent Predicate Device:** Abbott Laboratories' IMx® Rubella IgG  
K885297

**Description of Device:** IMMULITE Rubella IgG is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer

**Intended Use of the Device:** IMMULITE Rubella IgG is designed for the qualitative detection of IgG antibodies to Rubella virus in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the determination of immune status to rubella. This assay is particularly useful as an indicator of immune status for women of childbearing age.





### **Summary and Explanation of the Device:**

**IMMULITE® Rubella IgG** is a solid-phase, two-step, chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE® Test Unit, is coated with partially purified rubella antigen.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, rubella IgG in the sample binds to the rubella antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Test Unit is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for an additional 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus the photon output, as measured by the luminometer - is directly related to the presence of rubella IgG in the sample. A qualitative result is then obtained by comparing the patient result to an established Cutoff.

### **Performance Equivalence - Technology Comparison:**

Diagnostic Products Corporation (DPC) asserts that **IMMULITE® Rubella IgG** is substantially equivalent to the **IMx® Rubella IgG** kit marketed by Abbott Laboratories (*Abbott Park, IL*).

Each product is designed for the detection of IgG antibodies to rubella virus in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the determination of immune status to rubella.

**IMMULITE® Rubella IgG** is a chemiluminescent enzyme immunoassay, and **IMx Rubella IgG** is a microparticle enzyme immunoassay (MEIA). The technology in DPC's IMMULITE Rubella IgG is identical to technology used in previously cleared and commercially marketed IMMULITE® products.

In the **IMx Rubella IgG** assay, the patient sample and diluent buffer are added to predilution well of a reaction cell. Rubella virus coated microparticles and the diluted sample are added to an incubation well. The Rubella antibody binds to the Rubella virus coated microparticles, forming an antigen-antibody complex. Diluent buffer is added to the reaction mixture and an aliquot of the antigen-antibody complex is transferred to the glass fiber matrix. The microparticles bind irreversibly to the glass fiber matrix. The matrix is washed to remove unbound materials. The anti-human IgG/alkaline phosphatase conjugate is dispensed onto the matrix and binds to the antigen-antibody complex. Finally, the matrix is washed to remove unbound materials, the substrate, 4-Methylumbelliferyl Phosphate, is added to the matrix, and the fluorescent product is measured by the optical assembly.



**Performance Equivalence - Clinical Performance:**

The clinical performance of the IMMULITE Rubella IgG assay was studied at Diagnostic Products Corporation (DPC) using a Rubella proficiency panel obtained from the United States Centers for Disease Control and Prevention (CDC)

The in-house (DPC) retrospective study was conducted by assaying the CDC serum panel with the IMMULITE Rubella IgG assay, and sending the results to the CDC for unmasking. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

The panel consisted of 82% positive and 18% negative samples. The IMMULITE Rubella IgG assay demonstrated 98% total agreement with the CDC results. Of the results obtained by DPC, there was 98% agreement with the positive specimens and 100% agreement with the negative specimens.

Studies on the clinical performance of the IMMULITE Rubella IgG assay were also conducted at a university medical center located in the northwestern United States. A total of 300 serum specimens (previously collected and frozen by the investigators) were tested. Of the 300 specimens used in the prospective clinical study, 31 were from healthy, asymptomatic individuals undergoing a pre-employment screening, 256 were from pregnant women undergoing rubella screening and the remainder were obtained from female patients with miscellaneous diseases and conditions (AIDS, heart disease, immunocompromised, kidney transplant/dialysis). There were 9 male and 291 female subjects, with ages ranging from 11 to 57 years

All 300 specimens were evaluated with the IMMULITE Rubella IgG assay and the IMx Rubella IgG, an enzyme-linked fluorescent immunoassay (ELFA) which is commercially available on the IMx automated system

**IMMULITE Rubella IgG**

IMx	Positive	Indeterminate	Negative	Relative Sensitivity	Relative Specificity
Positive	271	1	2	99.3%	91.3%
Indeterminate	0	0	0		
Negative	2	3	21		

*Agreement: 98.6%*

*95% Confidence Limits for Relative Sensitivity and Specificity, respectively:*

*97.4% - 99.9% and 72.0% - 98.9%*

**Conclusion:**

The conclusions drawn from the clinical and nonclinical studies demonstrate that the device is safe, effective, and performs as well as, or better, than the current legally marketed devices.

*Edward M. Levine, Ph.D.*  
*Director of Clinical Affairs*

*Date*