K963245

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045
Tel: (213) 776-0180
Fax: (213) 776-0204

NOV 18 1996

510(k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045
Telephone Number:	(213) 776-0180
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	August 16, 1996
Device Name: **Trade:**	IMMULITE® Latex-Specific IgE Reagent system for detection of IgE antibodies to latex.
Catalog Number:	LKLXZ (50 tests), LKLX1 (100 tests)
Classification: **CLIA Complexity Category**	Class II device, 82-DHB (CFR 866.5750) Moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045
Establishment Registration Number:	DPC's Registration Number is 2017183
Substantially Equivalent Predicate Device:	Diagnostic Products Corporation's AlaSTAT® EIA Latex-Specific IgE Allergen (K931746) and AlaSTAT® Microplate Latex-Specific IgE Allergen (K)
Description of Device:	IMMULITE Latex-Specific IgE is a solid-phase, two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE Automated Analyzer.

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045
Tel: (213) 776-0180
Fax: (213) 776-0204

Intended Use of the Device:
DPC's IMMULITE Latex-Specific IgE is designed for the semi-quantitative detection of IgE antibodies specific to latex allergen in serum. It is intended strictly for in vitro diagnostic use as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Summary and Explanation of the test:
Hypersensitivity reactions were first reported to natural rubber latex by Nutter and have been reviewed recently by others. Latex is the milky sap of the rubber tree, *Hevea brasiliensis*, that is grown for commercial purposes. Type I immediate reactions to latex are caused by IgE antibodies specific for latex proteins. Clinical manifestations of these exposures include local urticaria, systemic urticaria, rhinitis, conjunctivitis, bronchospasm, and anaphylaxis.

Severe and fatal reactions have been observed in patients with no apparent prior risk factors. Nevertheless, factors exist which increase one's risk of latex allergy. According to the American Academy of Allergy and Immunology, risk factors include: previous allergic reaction to latex or latex-containing products; previous unexplained anaphylaxis; hand eczema; an allergic reaction like oral itching from crossreactive foods; spina bifida; and multiple surgeries in childhood.

Immunological crossreactivity between latex and certain foods, including banana, avocado, chestnut, and kiwi have been reported.

Current diagnosis of type I latex allergy is dependent solely upon the clinical history and physical examination of the patient. Other than *in vitro* testing for allergen specific IgE, finger or hand glove challenge has been suggested. Skin testing utilizing non-commercially available extracts has also been employed, although such testing carries with it attendant patient safety concerns.

Type IV reactions to latex-containing products are delayed, cell mediated reactions caused by sensitization to chemicals added during latex processing. Patch testing has been used to identify type IV reactions to latex.

Identification of latex-allergic individuals is the initial step in the process of patient education to prevent exposure and reactions in sensitive individuals.

Performance Equivalence:
Diagnostic Products Corporation (DPC) asserts that the IMMULITE Latex-Specific IgE system is substantially equivalent to both DPC's AlaSTAT® Microplate Latex-Specific IgE Allergen system and DPC's AlaSTAT™ EIA Latex-Specific IgE Allergen system. Each product is designed to measure circulating levels of IgE specific to latex in serum. Each product is intended strictly for in vitro diagnostic use to aid in the clinical diagnosis of IgE-mediated allergic disorders.

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045
Tel: (213) 776-0180
Fax: (213) 776-0204

Performance Equivalence - Technology Comparison:

IMMULITE Latex-Specific IgE is a chemiluminescent enzyme-labeled immunometric assay based on liquid ligand-labeled allergen complexes, monoclonal antibodies, and separation by an anti-ligand-coated solid phase. The IMMULITE Latex-Specific IgE assay exploits liquid-phase kinetics in a bead format. It represents a significant advance over conventional methods relying on allergens attached to a solid phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/copolymer matrix, which in turn is labeled with a ligand; anti-ligand is coated on the polystyrene bead to capture the ligand-labeled allergen complexes.

The patient sample and a ligand-labeled latex allergen are simultaneously introduced into the Test Unit, which contains an immobilized anti-ligand, and incubated for approximately 30 minutes at 37° C with intermittent agitation. During this time, allergen-specific IgE in the sample binds to the ligand-labeled allergen, which, in turn, binds to the anti-ligand on the solid phase. Unbound serum is then removed by a centrifugal wash.

Alkaline phosphatase-labeled monoclonal murine anti-IgE antibodies are 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 a further 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 also the photon output, as measured by the luminometer- is directly related to the amount of endogenous IgE specific for latex allergen.

The AlaSTAT Microplate Latex-Specific allergy test is a liquid-phase immunoenzymometric assay in a microplate format for the detection of circulating IgE antibodies to latex. The latex allergens are covalently attached to a soluble polymer/copolymer matrix, thus permitting opti num presentation of the determinants to circulating IgE antibodies. The AlaSTAT Microplate Latex-Specific allergy test is performed in the same manner as all other AlaSTAT Microplate Allergen-Specific IgE tests. Test results are given in both kilo-Units per liter (kU/L) and as a Class number.

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045
Tel: (213) 776-0180
Fax: (213) 776-0204

Performance Equivalence - Technology Comparison (continued):

The AlaSTAT EIA Latex-Specific allergy test is a liquid-phase immunoenzymometric assay in a tube format for the detection of circulating IgE antibodies to latex. The latex allergens are covalently attached to a soluble polymer matrix, thus permitting optimum presentation of the determinants to circulating IgE antibodies. The AlaSTAT EIA Latex-Specific allergy test is performed in the same manner as all other AlaSTAT EIA Allergen-Specific IgE tests. Test results are given in both International Units per milliliter (IU/mL) and as a Class number.

Performance Equivalence-Method Comparison:

Specimens from eighty-eight patient samples were evalutated using the IMMULITE Latex-Specific IgE assay compared to the AlaSTAT Microplate Latex-Specific IgE procedure yielding the following results: total agreement of 89.8%, relative sensitivity of 92.7% (95% CI: 82.4% - 98.0%), and relative specificity of 84.8% (95% CI: 68.1% - 94.9%).

Using the same patient population, the IMMULITE Latex-Specific IgE assay was compared to the AlaSTAT EIA Latex-Specific IgE procedure with the following results: total agreement of 89.8%, relative sensitivity of 91.2% (95% CI: 80.7% - 97.1%), and relative specificity of 87.1% (95% CI: 70.2% - 96.4%).

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the IMMULITE® Latex-Specific IgE.

Edward M. Levine

8/16/96

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

Date