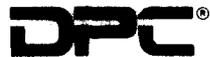


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Intended Use of the Devices:

DPC's AlaSTAT Microplate and AlaSTAT EIA specific allergen modules and mixed allergen panels are intended for use with the AlaSTAT Microplate and AlaSTAT EIA Allergen-Specific IgE systems in measuring allergen-specific circulating levels of specific IgE. They are intended strictly for *in vitro* diagnosis of IgE-mediated allergic disorders.

Summary and Explanation of the test:

Many allergies are mediated by immunoglobulins of the IgE class. In sensitized individuals suffering from this immediate (atopic or anaphylactic) type of allergy, IgE molecules act as points of contact between the allergen and specialized cells that release histamine and other agents upon exposure to the allergen; this initiates the events which we recognize as allergic reactions. When evaluated in the light of other clinical and laboratory findings, *in vitro* allergen-specific IgE tests can help the physician identify the allergen (or allergens) to which an individual is sensitive.

Technological Comparison to Predicate:

The AlaSTAT[®] Microplate and AlaSTAT[®] EIA Allergen-Specific IgE allergy tests are liquid-phase immunoenzymometric assays in microplate and tube formats respectively for the detection of circulating allergen-specific IgE antibodies. The specific allergens are covalently attached to a soluble polymer/copolymer matrix, thus permitting optimum presentation of the determinants to circulating IgE antibodies. The Specific Allergen Modules and Mixed Allergen Panels for the AlaSTAT[®] Microplate and AlaSTAT[®] EIA Allergen-Specific IgE systems are run in the same manner as all other AlaSTAT[®] Microplate and AlaSTAT[®] EIA Allergen-Specific IgE tests. Test results are given in kilo-Units per liter (kU/L) for AlaSTAT[®] Microplate and International Units per milliliter (IU/mL) for AlaSTAT[®] EIA, as well as a Class number for both formats.

The Pharmacia CAP System RAST[®] FEIA is an *in vitro* test system, based on ImmunoCAP technology for determination of circulating specific IgE antibodies. The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient serum specimen. To classify test results, fluorescence (FU) for patient samples are compared directly with FU for standards run in parallel. Test results are given in either kilo-Units per Liter (kU/L) or in Alternative Scoring Method (ASM) classes.



Performance Equivalence-Method Comparison:

The clinical performance of the AlaSTAT Microplate and AlaSTAT EIA Allergen-Specific IgE Systems were compared to one of the following [REDACTED] methods for each of the 63 allergens on patient samples, with results that support the conclusion that the device is as safe and effective, and performs as well as or better than the other legally marketed devices identified below.

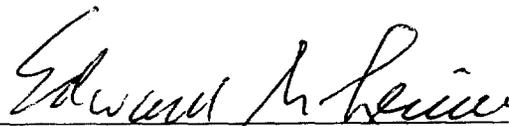
- Pharmacia CAP System RAST® FEIA
- AlaSTAT Microplate Allergen-Specific IgE
- AlaSTAT EIA Allergen-Specific IgE

Performance Equivalence:

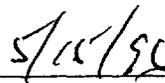
Diagnostic Products Corporation (DPC) asserts that the AlaSTAT® Microplate and AlaSTAT® EIA Allergen-Specific IgE systems produce substantially equivalent IgE results to other commercially marketed allergen-specific IgE assays. Each product is intended strictly for *in vitro* diagnostic use to aid in the clinical diagnosis of IgE-mediated allergic disorders.

Conclusion:

The information presented in this summary of safety and effectiveness is the information that the Food and Drug Administration used in granting DPC substantial equivalence for the additional Specific Allergen Modules and Mixed Allergen Panels for AlaSTAT Microplate and AlaSTAT EIA Allergen-Specific IgE Systems.



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



Date