

## Hitachi Chemical Diagnostics' CLA® Allergy Test **Clinical Confirmation**

### Correlation to Pharmacia CAP®

"This preliminary study in 60 atopic patients shows a good agreement between the HCD CLA and Pharmacia CAP immunoassays with regard to their ability to detect the presence or absence of specific IgE in serum."

Bucher, C, et al, *Measurement of Specific IgE to Inhalant Allergens with the HCD CLA and the Pharmacia CAP Immunoassays: a Method Comparison Study*, presented at the oral poster session, European Academy of Allergology and Clinical Immunology, May, 2002, Naples, Italy

"The results of this evaluation showed that the CLA assay has a comparable analytical performance to the Pharmacia CAP System. The CLA panel that allows the simultaneous test of up to 36 allergens can now be positioned as a valuable and reliable tool in the diagnosis of allergic disease."

Bonete, J, Buendia, E, *Comparison between Skin Prick Testing and Specific IgE Measurements for Diagnostic Evaluation of Patients with Inhalant Allergies*, presented at the oral poster session, International Congress of Allergology and Clinical Immunology, October, 2000, Sydney, Australia

### Correlation to SPT

"Both CLA and CAP show a 93% concordance vs SPT."

Pfannenstiel, C, et al, *Sensitivity and Specificity Evaluation Study in Pediatric Patients: CLA Atopy Panel 20 and CAP-FEIA-System vs Skin Prick Test as "Gold Standard,"* *Pediatric Allergology*, March, 2001; 15-19, Aachen, Germany

"The CLA assay for allergen specific IgE offers reliable results concordant with skin test.... Potential advantages of in vitro assays (include) diagnosing inhalant allergy in selected patients in whom skin tests cannot be performed."

Christensen, S N, Backer, V, DuBuske, L M, Nolte, H, *In Vitro Diagnostic Evaluation of Patients with Inhalant Allergies*, *Allergy and Asthma Proceedings*, July-August 2003, Vol. 24, No. 4.

### Front-line Panel Testing

"We found that selective panel testing using in vitro allergen specific IgE tests may be useful as front line tests in evaluating inhalant allergy in subjects suffering of allergy symptoms in order to identify patients who should be referred to allergy specialist for treatment and further evaluation."

Nolte, H, *Undiagnosed Asthma & Allergy; Nursing & Patient Care - Allergy Diagnosis*, Private Hospital Healthcare Europe; 2001

### Technology and Cost Evaluations

"Given their respective trajectories for technological advancement, quantification and quality control, in vitro testing may offer the more standardized approach (vs SPT)."

Poon, A, et al, *In Vitro and Skin Testing for Allergy: Comparable Clinical Utility and Costs*, *The American Journal of Managed Care*, July 1998, Vol. 7, No. 4.

"While once considered more costly than skin testing, modern screening methods make in vitro allergy testing no more costly than skin testing. Many insurers have incorporated these cost-saving screen into their coverage guidelines."

Corey, J P, *Executive Summary*, American Academy of Otolaryngic Allergy, March 1997