

A close-up photograph of a man and a young girl in a field of yellow flowers. The man, on the left, has dark hair and a goatee, and is looking down at the girl. The girl, on the right, has brown hair in a ponytail and is wearing a pink cardigan with a butterfly and floral patterns. She is holding a yellow flower. The background is a soft-focus green field.

TECHNOLOGY IN ACTION

CLA[®] | ALLERGEN-SPECIFIC IgE ASSAY

Helping the medical community provide
quality and affordable allergy care.

HITACHI
Inspire the Next

Helping the
Medical
Community

One out of every five people suffers from some form of allergy.^{2,3} Treating these allergies can be a challenge, but first an accurate diagnosis must be made.

In today's cost-conscious healthcare environment, a doctor's ability to refer allergy patients to a specialist may be diminished. Patients also prefer efficient, high quality diagnosis that allows prompt and effective health management.

Always known for technology and reliability, Hitachi offers the medical community an alternative means of diagnosing allergy in a timely manner and at a significantly lower cost than has traditionally been available. We're proud to present an accurate, easy to use serum test for allergy—the **CLA Allergen-Specific IgE Assay**.

Used as part of an initial allergy evaluation, the information obtained allows optimal patient management by avoiding unnecessary and costly referrals of non-allergic patients, while allergic patients can be treated sooner and more effectively.



Quality & Affordable
Allergy Care

Hitachi Quality	Accurate test results offer good correlation with skin testing. Access to the latest <i>in vitro</i> allergy testing technology.
Objective Analysis	Up to 36 specific IgE results—optimized with the most regional or categorically prevalent allergens—from a 1.5 ml serum sample.
Easy to Use	CLIA Moderate Complexity system requires minimal training and provides plenty of “walk-away” time for staff to perform other duties.
A Cost-Effective System	Easily incorporated with existing licensing, personnel and space. Low start-up costs and incremental revenue help grow a physician's practice.
CLA-1™ Technology	User-friendly instrument, including a small footprint on the lab bench. Reads up to 180 allergens, or five panels, in less than ten minutes.
Comfortable for Patients	A less intrusive technique that can be performed without stopping current medications and regardless of skin condition.
Consultation & Education	A board-certified allergist is available to discuss test results, treatment options and other aspects of allergic disease. Educational materials for patients are also available.

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 screens into their coverage guidelines.⁴

² Sly RM, Changing prevalence of allergic rhinitis and asthma, *Annals of Allergy, Asthma & Immunology*, Vol 82, March 1999, p233-248.
³ Nolte, H, *Undiagnosed Asthma & Allergy; Nursing & Patient Care— Allergy Diagnosis*, Private Hospital Healthcare Europe; 2001.
⁴ Corey, J P, *Executive Summary*, American Academy of Otolaryngic Allergy, March 1997.

The CLA Allergen-Specific IgE Assay

The system, which consists mainly of the **CLA Pette** and the **CLA-1™ Luminometer**, simultaneously measures the severity of a patient's allergic reaction to up to 36 different allergens using a single 1.5 ml serum sample.

The **CLA Pette**, a small plastic device, is the fundamental component of the system. Each device contains up to 36 cellulose threads, each bound with a selected allergen.

Counterpart to the **CLA Pette**, the **CLA-1 Luminometer** completes the allergy testing system. This bench-top instrument reads prepared **CLA Pettes**, measuring the amount of chemiluminescent light emitted by the reaction to each allergen. In less than ten minutes,

it can analyze up to 180 allergens. The instrument automatically prints a complete report that lists the tested allergens and the severity of the patient's response to each.



> CLA Pette

The **CLA-1 Luminometer** performs a self-diagnostic each time it is powered up to ensure correct results. FDA-cleared and CE-marked, it has shown consistent, reliable performance in laboratories around the world.

The system uses Hitachi's patented chemiluminescence technology, one of the most sensitive detection systems available. This allows for the detection of very low levels of IgE in patient serum. Hitachi also holds patents on the **CLA Pette** and its binding technology.

The **CLA Allergen-Specific IgE Assay** serves allergy patients worldwide, so each panel is designed to be geographically specific. Physicians simply select the panel that's most appropriate for their patient.

- **Inhalant panels** – pollen, dust, mites and other airborne regional allergens.
- **Food panels** – commonly ingested foods such as peanut, milk, tomato, soybean, wheat and others.
- **Combination panels** – up to 36 of the most prevalent food and inhalant allergens overall.

The pre-determined panel format simplifies testing and reduces set-up time. It also eliminates inventory of individual allergens and decreases waste.

“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.

Given their respective trajectories for technological advancement, quantification and quality control, in vitro testing may offer the more standardized approach (vs. SPT).⁵

⁵ 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.

Allos Reference Laboratory

Hitachi Chemical Diagnostics is committed to improving the lives of allergy patients. In addition to its proven product line, the company also offers extensive service and support with its **Allos Reference Laboratory**—an ideal alternative for physicians who want to provide their patients with a less invasive, world-class allergy diagnosis when internal testing facilities are not available.



> Allos Reference Laboratory.

Consultation & Education

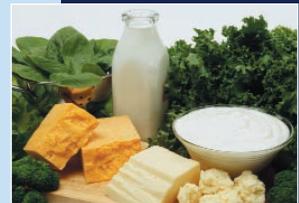
A board-certified allergist is available to discuss test results, treatment options and other aspects of allergic disease. The lab also provides educational materials and patient history forms.

Objective Analysis

The **Allos Reference Laboratory** has one function only: allergy testing. Physicians simply submit a patient's serum sample and select the **CLA Allergen-Specific IgE Assay** panel of their choice.

Quick Turnaround

The laboratory provides request forms, pre-paid over-night express mailers and serum vials to all its customers at no charge. In approximately three working days, physicians receive a precise, objective analysis of the patient's reaction to each allergen.



Inhalant Panels



Combination Panels



Allergies are the 6th leading cause of chronic disease in the United States, costing the health care system \$18 billion annually.¹

¹ American Academy of Allergy, Asthma and Immunology (AAAAI). *The Allergy Report: Science Based Findings on the Diagnosis & Treatment of Allergic Disorders*, 1996-2001.

Ⓒ Hitachi Chemical Diagnostics, Inc.

With its headquarters in the heart of Silicon Valley and offices around the world, Hitachi Chemical Diagnostics is a global leader of *in vitro* allergy diagnostics with a legacy of innovation. Hitachi Chemical Diagnostics was the first company to introduce a multiple *in vitro* diagnostic test for allergies and one of the first to introduce a chemiluminescent assay system for the detection of IgE antibodies. The company holds many *in vitro* allergy testing technology patents and continues to pioneer advancements in the field.

Hitachi Chemical Diagnostics, an integral member of the Hitachi Group, works with industry leaders, laboratories and distributors around the world to provide the medical community access to the latest *in vitro* allergy testing technology. Hitachi Chemical Diagnostics is committed to innovation, quality, and the strength of the Hitachi brand. Our products are marketed to over 40 countries worldwide. To learn more about Hitachi Chemical Diagnostics and CLA, please contact us or your local representative, or visit us on the web at www.hcdiagnostics.com.

United States Office

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