

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 looking at a yellow flower held in her hands. She is wearing a pink cardigan with a butterfly and floral patterns. The background is a soft-focus green field.

TECHNOLOGY IN ACTION

CLA<sup>®</sup> | 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.<sup>2,3</sup> 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.<sup>4</sup>

<sup>2</sup> Sly RM, Changing prevalence of allergic rhinitis and asthma, *Annals of Allergy, Asthma & Immunology*, Vol 82, March 1999, p233-248.  
<sup>3</sup> Nolte, H, *Undiagnosed Asthma & Allergy; Nursing & Patient Care— Allergy Diagnosis*, Private Hospital Healthcare Europe; 2001.  
<sup>4</sup> 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).<sup>5</sup>

<sup>5</sup> 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.

## 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.<sup>1</sup>

<sup>1</sup> 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](http://www.hcdiagnostics.com).

### United States Office

#### Ⓢ Hitachi Chemical Diagnostics, Inc.

630 Clyde Court  
Mountain View  
CA 94043-2239  
650.961.5501  
800.233.6278  
[www.hcdiagnostics.com](http://www.hcdiagnostics.com)

### European Office

#### Ⓢ Hitachi Chemical Diagnostics, Inc.

Hitachi Europe Ltd.  
Whitebrook Park  
Lower Cookham Road  
Maidenhead, Berkshire, SL6 8YA  
United Kingdom  
44 (0) 1628.585.590

CLA is a registered trademark and CLA-1 is a trademark of Hitachi Chemical Diagnostics, Inc., in the United States and/or other countries worldwide.

Hitachi Chemical Diagnostics, Inc.  
 CPT & ICD-9 Diagnostic Codes

## CLA<sup>®</sup> Allergen-Specific IgE Assay

The following CPT Codes are identified courtesy of the AMA CPT Code Book. Hitachi Chemical Diagnostics is happy to provide this information, but cannot be liable for any misfiled claims.

<u>Description</u>	<u>CPT Code</u>
Allergen Specific IgE; Quantitative or Semiquantitative, Each Allergen (12 allergen panel x 12; 25 allergen panel x 25; 36 allergen panel x 36).....	86003
It is the physician's responsibility to determine which code to use when billing for specific procedures and services. ICD-9 Diagnostic codes commonly associated with <i>in vitro</i> allergy testing are listed as they appear in the current ICD-9-CM Code Book.	
372.14..... Other chronic allergic conjunctivitis	493.90 - 493.92 +..... Asthma, unspecified, unspecified
381.00 - 381.06 +..... Acute nonsuppurative otitis media, Unspecified - Acute allergic sanguinous otitis media	- Asthma, unspecified with (acute) exacerbation
381.10..... Chronic serous otitis media, simple or unspecified	691.8..... Other atopic dermatitis and related conditions
381.19..... Other chronic serous otitis media	692.9..... Contact dermatitis and other eczema, unspecified cause
381.3..... Other and unspecified chronic nonsuppurative otitis media	693.0..... Dermatitis due to drugs & medicines
381.4..... Nonsuppurative otitis media, not specified as acute or chronic	693.1..... Dermatitis due to food
381.50 - 381.52 +..... Eustachian salpingitis, unspecified - Chronic Eustachian salpingitis	693.8..... Dermatitis due to other specified substances taken internally
381.81..... Dysfunction of eustachian tube	693.9..... Dermatitis due to unspecified substance taken internally
382.9..... Unspecified otitis media	708.0..... Allergic urticaria
466.0..... Acute bronchitis	708.8..... Other specified urticaria
471.0..... Polyp of nasal cavity	708.9..... Urticaria, unspecified
471.1..... Polypoid sinus degeneration	781.1..... Disturbances of sensation of smell and taste
471.8..... Other polyp of sinus	782.1..... Rash and other nonspecific skin eruption
471.9..... Unspecified nasal polyp	786.00..... Respiratory abnormality, unspecified
472.0..... Chronic rhinitis	786.05..... Shortness of breath
474.00 - 474.02 +..... Chronic tonsillitis and adenoiditis - Chronic tonsillitis and adenoiditis	786.07..... Wheezing
474.10 - 474.12 +..... Hypertrophy of tonsils with adenoids - Hypertrophy of adenoids alone	786.2..... Cough
477.0..... Allergic rhinitis due to pollen	989.5..... Toxic effect of venom
477.1..... Allergic rhinitis due to food	989.82..... Toxic effect of latex
477.2..... Allergic rhinitis due to animal (cat) (dog) hair and dander	995.0..... Other anaphylactic shock
477.8..... Allergic rhinitis due to other allergen	995.1..... Angioneurotic edema
477.9..... Allergic rhinitis cause unspecified	995.20 - 995.23 +..... Unspecified adverse effect of unspecified drug, medicinal and biological substance
478.11..... Nasal mucositis (ulcerative)	- Unspecified adverse effect of insulin
478.19..... Other disease of nasal cavity and sinuses	995.27..... Other drug allergy
493.00 - 493.02 +..... Extrinsic asthma, unspecified - Extrinsic asthma with (acute) exacerbation	995.29..... Unspecified adverse effect of other drug, medicinal & biological substance
493.10 - 493.12 +..... Intrinsic asthma, unspecified - Intrinsic asthma with (acute) exacerbation	995.3..... Allergy, unspecified
493.20 - 493.22 +..... Chronic obstructive asthma, unspecified - Chronic obstructive asthma with (acute) exacerbation	995.60 - 995.69 +..... Anaphylactic shock due to unspecified food - Anaphylactic shock due to other specified food
	995.7..... Other adverse food reactions, not elsewhere classified

Hitachi Chemical Diagnostics, Inc.  
**Allergy ROI Table**

<u>Equipment</u>	
CLA-1 Luminometer	\$ 12,000.00
<u>Monthly Operating Costs</u>	
Hitachi Reagents	\$ 1,760.00
Hitachi Controls	\$ 155.93
Hitachi Supplies	\$ 4.40
CLIA Fees	\$ 41.67
Proficiency Testing	\$ 69.79
Total	\$ 2,031.79
Gross Cost Per Test	\$ 92.35
<u>Monthly Gross Revenue</u>	
Reimbursement / Test	\$ 268.92
Tests / Month	22
Total	\$ 5,916.24
<u>Gross Profits</u>	
Monthly Revenue	\$ 5,916.24
Monthly Operating Costs	\$ 2,031.79
<b>Monthly P / L</b>	<b>\$ 3,884.45</b>
<b>Months to Break Even</b>	<b>&lt; 4</b>
<b>Annual Total</b>	<b>\$ 46,613.38</b>
<b>Margin</b>	<b>66%</b>
<b>Monthly ROI</b>	<b>191%</b>

Today's primary care physician is the gatekeeper for millions of Americans suffering from allergy. Most patients are diagnosed and referred to a specialist simply on the basis of medical history and clinical symptoms. The complexity of allergy as a disease makes this approach less than ideal.

Primary care physicians need to be equipped with the tools to provide basic diagnosis and management of the allergic population. The *CLA® Allergen-Specific IgE Assay* helps clinicians make an accurate diagnosis and avoid unnecessary and costly referrals and prescriptions.

To learn more about The *CLA® Allergen-Specific IgE Assay*, contact your local representative, call Hitachi at 1 800 233 6278 or e-mail [sales@hcdiagnostics.com](mailto:sales@hcdiagnostics.com).

Reprinted Courtesy of CAP Today,  
a newsmagazine published by the  
**College of American Pathologists**  
All rights reserved  
www.cap.org



## **(A)topic of concern: omitting specific IgE tests**

**Published: March 2007, Feature Story**

**By Anne Ford**

Call it the no-brainer of the week: If a patient comes to her primary care physician and reports frequent urination, extreme thirst, and a family history of diabetes, what is the appropriate clinical response?

"I would never say to the patient, 'You might have it [diabetes]. Take this medicine, see me in a month, and I'll see how you're doing,'" said Leonard Fromer, MD, an allergist and family physician from Santa Monica, Calif.

"It's pretty clear that for most of the atopic disease presentations, we're doing a lot of, 'Try this and see if it works,' rather than using specific IgE testing to 'make an informed, evidence-based decision.'"

But that's more or less what many clinicians do when diagnosing patients with allergies, he asserts. "It's pretty clear that for most of the atopic disease presentations, we're doing a lot of, 'Try this and see if it works,'" rather than using specific IgE testing to "make an informed, evidence-based decision," Dr. Fromer said.

In "Advances in IVD Allergy Testing"—a recent audioconference offered by the American Association for Clinical Chemistry—Dr. Fromer and P. Brock Williams, PhD, clinical research professor, allergy and clinical immunology, at the University of Missouri, Kansas City, discussed the importance of specific IgE measurement and its potential to enhance patient care.

"Despite the fact that medically significant allergies are becoming more widespread," Dr. Williams said, "most cases are still diagnosed simply on the basis of medical history, perhaps medication challenges, clinical symptoms, and skin testing or food challenges." The complexity of allergy as a disease, he pointed out, makes this approach less than ideal: "The symptoms are quite common and have a number of other different causes that are not mutually exclusive. There are primary and secondary inflammatory effects and...temporal relationships with exposure, but sometimes these temporal relationships aren't completely clear."

In addition, most allergy patients are sensitive to more than one allergen, and untreated allergic symptoms can result in serious, even fatal complications such as anaphylaxis. Add to that an estimated \$17 billion in annual allergy-related health care costs, and the value of objective specific IgE testing becomes even more apparent.

Those costs stem in part from what Dr. Fromer calls "the allergy march," that is, the symptom progression of many atopic patients. They often begin life as infants with eczema,

then turn into toddlers with food allergies, older children with recurrent ear infections, preteenagers with rhinosinusitis, and ultimately, adolescents and adults with asthma. That progression, Dr. Fromer says, "is played out against the exposure to triggers, which very much determines the consequences in terms of clinical signs and symptoms. If we know what the triggers are...[and] teach the patients to get below their symptom threshold for those triggers, we can greatly modify the expression of that gene in these patients."

He points out, too, that there are 21 million asthmatics in the United States and that asthma is overwhelmingly an allergic disease. "The NIH asthma guidelines...speak towards this and speak towards using testing, either in vitro serum IgE or on the skin, to identify persistent asthmatics and their triggers."

So why are some clinicians slow to recognize the value of specific IgE testing? As Dr. Fromer acknowledged, "A lot of them say, 'Why do we need to test a patient if they walk in and say they absolutely positively know it's ragweed, or they know it's cats, or they know it's dust?' Well, the answer is, even though they may be right about that trigger, that's not the complete story." For example, patients who can tell they're sensitive to ragweed may be unaware that they're sensitive to several other allergens as well, which don't produce symptoms until they're exacerbated by the presence of ragweed.

'Why do we need to test a patient if they walk in and say they absolutely positively know it's ragweed, or they know it's cats, or they know it's dust?' Well, the answer is, even though they may be right about that trigger, that's not the complete story."

Furthermore, the likelihood of a patient obtaining a prescription for allergy medication is often driven to an inappropriate degree by the preference of that patient, Dr. Fromer said.

"... A 2004 study... found that 65 percent of patients who requested allergy medication from their physicians and had been placed on a nonsedating antihistamine were on the wrong medication. They were not atopic and had other etiologies for their allergy-like symptoms."

Direct-to-consumer advertising, the prevalence of medical information on the Internet, and the current allergy epidemic have produced patients who are "convinced they have allergies if they have symptoms from the neck up, and they want medication." He cited a 2004 study that found that 65 percent of patients who requested allergy medication from their physicians and had been placed on a nonsedating antihistamine were on the wrong medication. They were not atopic and had other etiologies for their allergy-like symptoms (Szeinbach SL, et al. *J Manag Care Pharm.* 2004; 10(3): 234-238).

Clinicians making an allergy diagnosis over-rely, too, on patient history, Dr. Williams said. He used decision theory to explain why patient history should not be considered the gold standard for diagnosis. First, simply because patients have gone to an allergist, the unconscious assumption is that they must therefore have allergies, when that may not be the case. Second, "a lot of times someone will anchor to one particular item in the history and then not pay attention to anything else," he said. In addition, the so-called availability error means that physicians sometimes make the mistake of thinking that, for example, if Patient A is allergic to pollen, Patient B resembles Patient A, and the pollen count is high, Patient B must be allergic to pollen. Finally, fear of missing something in a patient's history makes some physicians more likely to overpredict the number of allergens to which the patient is sensitive.

In a 2003 study, Dr. Williams and his coauthors compared patient history with concordant skin tests and specific IgE measurements to seven common allergens (*Ann Allergy Asthma Immunol* 2003; 91: 26– 33). They found that history and physical examination alone rarely exceeded 50 percent accuracy. “That’s essentially flipping a coin,” Dr. Williams pointed out.

“History and physical examination alone rarely exceeded 50 percent accuracy.”

But what about other methods? Allergen provocation testing is somewhat cumbersome and not particularly accurate, Dr. Williams said. Medication trials overlook the fact that many medications are nonspecific, have side effects, or are not particularly effective. “There have been studies on Claritin that showed that it’s only three percent over placebo,” he pointed out, “and so a medication trial is obviously not going to give you a good answer on that.” And as for prick and other dermal tests, “they essentially are not standardized, the extracts

“Specific IgE tests stand out as ‘the only tests in this group that are actually objective.’”

are not defined, the methods differ, even the devices differ in different offices. There are interpretive problems, and we really don’t know what the rate of false positivity or false negativity or the sensitivity or the specificity of the skin tests actually are.” Against this dismal backdrop, specific IgE tests stand out as “the only tests in this group that are actually objective.”

Dr. Williams summarized the history of IgE testing: “From ‘74 to ‘92, we saw quite a few different varieties of tests for IgE on the commercial market. And these all involved a lot of differences. These differences included different sources of allergens, the allergen extracts, there were different coupling chemistries introduced, different solid phases. The detection using enzymes as opposed to radioisotopes was introduced, along with monoclonal or mixtures of monoclonal antibodies to improve the specificity of the test. And all these tests worked, but not to the same extent. Unfortunately, all these tests were referred to as RAST [radioallergosorbant] tests...which is very unfortunate, because it doesn’t distinguish between tests that perform well and not so well,” he said.

The most gratifying part of current IgE efforts, he added, “is that where the real progress is being made, we are now generating risk ratios and probability curves that are related to the specific IgE a patient has in their serum.”

In 2001, Dr. Williams and three coauthors conducted a study of three specific IgE testing methods (*Ann Allergy Asthma Immunol* 2001; 86: 373–381). “We had an n of 12,708 results, which we analyzed for precision, accuracy, and quantitative ability for each allergen in the study,” Dr. Williams said. The authors discovered that the three methods varied widely in their precision, which they measured by the percent CV of triplicates of the positive responses: “For some allergens the precision was not that bad, and some it was quite bad.” Why is this important? “Well, we’ve now come to understand that the level of specific IgE in the serum is certainly related to the probability of an individual having symptoms when they’re exposed to that particular allergen,” he said. “If you have a CV of around 25 percent, then that essentially covers a very large part of this curve and makes it very difficult to use this relationship.”

A year before, Dr. Williams and three coauthors had published a study on the accuracy and quantitative ability of three IgE methods via dilutional analysis (*J Allergy Clin Immunol* 2000; 105: 1221–1230). Quantitation is important, Dr. Williams said, “because we can now relate the amount of IgE antibody people are producing to the probability that they’re

having symptoms." In this regard, the questions to ask are: Are dilutions of samples parallel to the calibrator? Does this occur over the stated range? If so, is this true for all allergens? What is the standard used for comparison? Can an imprecise assay be quantitative?

The study authors discovered that on a dichotomous basis, the methods agreed fairly well. "However, if we look at a logarithmic Bland-Altman plot, which is essentially taking one [method] as a standard and comparing the other two results across the assay range, we can show...that the results are not similar at all," Dr. Williams said. "We don't know which one is right from this analysis, but we can certainly say that for any of these assays, the results do not correlate very well with the other assays." Conclusion: Results from the different assays cannot be used interchangeably, and studies on clinical interpretations must be performed for each method alone.

To determine which assay produced the best results, the study authors used chimeric antibodies, that is, humanized mouse monoclonal antibodies with the human IgE constant portion of IgE and specificity for the major allergens of mite and birch. "We found that one assay essentially correlated very well with the standard," Dr. Williams said. "But we found one assay essentially did not report very much specific E for any of these dilutions, whereas one assay way overestimated the amount of IgE in these samples."

"I might point out," he added, "that if you took any of these curves by themselves, they look fairly linear. So people can publish curves that look like they are linear and giving good quantitative results, but until they compare it to a standard such as a chimeric antibody, they don't know if that linear curve is actually accurate or not. I would caution people to read the literature carefully and consider the source. We've seen clear-cut examples of selective use of data, improper use of statistics, publications in low-impact journals, which are generally not reviewed as vigorously as high-impact journals, leading to some rather questionable studies and the clear-cut fact that these are essentially marketing studies."

Finally, Dr. Williams advised participants to watch later this year for the updated version of a consensus document from the Clinical and Laboratory Standards Institute that delineates some of the characteristics of the specific IgE tests and the kind of proficiencies they should

"The scoring of the specific IgE is either quantitative or semiquantitative, whereas the skin test is really very subjectively graded from a one plus to a four plus.

meet. "There's nothing like this for skin testing," he pointed out. "The scoring of the specific IgE is either quantitative or semiquantitative, whereas the skin test is really very subjectively graded from a one plus to a four plus. It's really nice that with the specific IgE test you can actually show that you're measuring what you think you're measuring, so we can show specificity and we can show analytical sensitivity in how sensitive these assays are, with statistics, and neither of these are known for skin testing."

Dr. Fromer, meanwhile, ended by emphasizing how specific IgE testing can contribute to a new health care paradigm of evidence-based treatment. Too often we immediately "throw medicine at people," he says. In the case of allergies, that often means neglecting to use specific IgE testing to help allergy patients determine their triggers so they can, if possible, minimize their exposure to them. "We go right past available objective testing, in this case right past IgE, right past lifestyle change," he says. "It makes no sense. We have to get away from that. We have to use the tools we have—that is, IgE—to get evidence, to do better for the patients."

Hitachi Chemical Diagnostics, Inc.  
2009 Price List

**HITACHI**  
Inspire the Next

## CLA-1™ Luminometer

Prices are subject to change without notice as HCD continues to improve its product line.

### CLA-1 Equipment and Accessories

Product Code	Product Name	List Price
95013	CLA-1 Luminometer System Includes CLA-1 instrument, start-up reagents, equipment kit, control serums, transformer, controller, 2 Pette cassettes, program card, operator's manual, printer paper and spindle.	\$12,000.00
95136	Universal Equipment Kit Included with purchase of CLA-1 at no charge.	\$800.00
90020	CLA® Pette Cassette (Each holds 5 CLA Pettes)	\$500.00
90050	CLA-1 LED Control	\$650.00
90355	CLA-1 Program Card (U.S. English)	\$250.00

### CLA-1 Equipment Kit, Individual Components

Product Code	Product Name	List Price
90040	Work Station Rack, holds 40 Pettes	\$90.00
90045	Work Station Reservoir, receptacle used with rack (#90040)	\$75.00
94025	Wash Buffer Dispenser, 2,000 mL bottle and repeating bottle top dispenser, 10 mL	\$290.00
70083	Wash Buffer Dispenser Cap Replacement	\$10.00
70502	Micropipette, 0.5 - 5,000 µL	\$209.00
70503	Disposable Tips, for use with Micropipette (#70502), 100 tips per package	\$20.00
70103	Disposable Reagent Cups, 50 mL, 100 per package	\$30.00
70013	Disposable Reagent Cups, 5 mL, 100 per package	\$15.00
60500	User Guide and Procedural Manual	\$35.00

### Supplies

Product Code	Product Name	List Price
70140	Printer Ribbon for Impact Printer	\$9.00
70243	Transformer, 110-120 V	\$400.00
70269	Printer Paper, Thermal, for CLA-1	\$10.00
80070	CLA Pette Plugs, Bottom, 11 per package	\$5.00
80075	CLA Pette Plugs, Top, 11 per package	\$5.00
94081	Serum Vials (blue cap), 100 per package	\$25.00
Doc. No. 0277	CLA-1 Luminometer Operator Manual	\$25.00

To learn more about The CLA® Allergen-Specific IgE Assay, contact your local representative, call Hitachi at 1 800 233 6278 or e-mail sales@hcdiagnostics.com.

www.hcdiagnostics.com  
Doc. No. 0827 Rev. 00

© 2009 Hitachi Chemical Diagnostics, Inc. All rights reserved.

CLA is a registered trademark and CLA-1 is a trademark of Hitachi Chemical Diagnostics, Inc. in the United States and other countries.

Hitachi Chemical Diagnostics, Inc.  
2009 Price List

## CLA<sup>®</sup> Allergy Test

Prices and panels are subject to change without notice as HCD continues to improve its product line.

### Regional 36-Allergen IgE Panels

Each kit includes CLA<sup>®</sup> Pettes and reagents sufficient for 20 tests.

Product Code	Product Name	List Price
84502	Eastern Panel (combines IgE foods and inhalants)	\$1,600.00
84504	Northeastern Inhalant Panel	\$1,600.00
84505	Northwestern Inhalant Panel	\$1,600.00
84506	Pediatric Comprehensive Panel (combines IgE foods and inhalants)	\$1,600.00
84507	Southeastern Inhalant Panel	\$1,600.00
84508	Southern Panel (combines IgE foods and inhalants)	\$1,600.00
84509	Southwestern Inhalant Panel	\$1,600.00
84510	Western Panel (combines IgE foods and inhalants)	\$1,600.00
84511	Western Inhalant Panel	\$1,600.00
84518	Moderate Food Panel	\$1,550.00
84521	US 12 Inhalant	\$1,000.00
84522	US 12 Food	\$1,000.00
84523	US 15 Mixed	\$1,000.00
84524	US 24 Inhalant	\$1,550.00
Doc. No. 0508	Test Records	N/C

### CLA IgE Controls (CLA Reference Material)

Product Code	Product Name	List Price
93026	Positive Control Serum (3 x 3 ml)	\$110.00
94173	Negative Control Serum (3 x 3 ml)	\$110.00

### CLA IgE Reagents (included in Test Kits)

All components listed below are sufficient for 20 tests.

Product Code	Product Name	List Price
93130	IgE Antibody	\$20.00
93105	Wash Buffer Concentrate	\$20.00
93101	Photoreagent A	\$20.00
93102	Photoreagent B	\$20.00
93103	Photoreagent C	\$20.00
93104	Photoreagent D	\$20.00

To learn more about The CLA<sup>®</sup> Allergen-Specific IgE Assay, contact your local representative, call Hitachi at 1 800 233 6278 or e-mail sales@hcdiagnostics.com.

www.hcdiagnostics.com  
Doc. No. 0828 Rev. 00

© 2009 Hitachi Chemical Diagnostics, Inc. All rights reserved.

CLA is a registered trademark and CLA-1 is a trademark of Hitachi Chemical Diagnostics, Inc. in the United States and other countries.

# ***CLA-1<sup>TM</sup> Luminometer***

## **Illustrated Protocol Summary**



Prepare Pettes

Centrifuge all serum samples at 3000RPM for 10-15 minutes prior to filling the *CLA<sup>®</sup>Pettes*. Remove the Pettes from the kit (one per sample), wipe the moisture from the outside of each Pette and label each with sample identification.



Draw serum into Pettes

Attach a syringe into the top of the Pette and draw serum into the Pette, making certain the top thread is covered. With the syringe still attached to the top, place the bottom plug into the Pette. Remove the syringe and plug the top.



Plug Pettes

Store the serum-filled pettes upright in a workstation and incubate at room temperature for 16-24 hours, noting the time incubation is started.

At the conclusion of incubation, drain the serum into the workstation reservoir by removing the bottom plug, then the top plug. Retain the plugs for use in subsequent steps.



Drain Pettes

Prepare wash buffer by adding 50ml of Wash Buffer Concentrate to 950ml of distilled water, mixing thoroughly. Wash each Pette with 10ml of wash buffer three times.

Use the syringe to draw the antibody reagent into each Pette, until the top thread is covered. Plug the bottom and top of the Pettes. Incubate the pettes at room temperature for four hours, noting time incubation is started.



Wash Pettes

When finished incubating the antibody, drain the Pettes as before, washing them thoroughly three times with wash buffer solution, and draining thoroughly.



Prepare chemiluminescent photoreagent

To prepare the chemiluminescent photoreagent, refer to the "Reagent Preparation Table" (Doc. No. 0528). Using the pipette, dispense the recommended amount of each photoreagent (A, B, C, D) into the 50 ml disposable cup.



Draw photoreagent into Pettes

Use a syringe to draw the photoreagent mixture into each Pette, until the thread is covered. Plug the bottom and top. Note: Set a timer for ten minutes as soon as the first pette is filled. It is important to allow the test chambers to stand for ten minutes prior to *CLA-1 Luminometer* reading to assure stable light output from the allergen threads.



Load cassette tray into *CLA-1 Luminometer*

Wipe the Pettes dry and place them (1-5) in the cassette tray. Load the cassette tray into the *CLA-1 Luminometer*. Note: the cassette tray can only be loaded into the *CLA-1 Luminometer* by pressing the "Open/Close" button on the transport door. Depressing the button again, after the cassette tray has been loaded will close the transport door.



Read and print test results

Program the *CLA-1 Luminometer* by identifying the Pette test chambers in the cassette with the "Load List" presented by the *CLA-1 Luminometer* screen. Pressing the "Up" or "Down" buttons on the *CLA-1 Luminometer* will scroll through the panel selections corresponding to the Pette test chambers in the cassette tray. Press "Enter" at the appropriate selection matching the display with the test chamber. Repeat this process until all test chambers within the cassette tray have been properly identified. A new "Load List" will appear on the display. If it correctly matches the test chambers, press "Enter" and the *CLA-1 Luminometer* will scan/read the test chambers and print the test results in approximately eight minutes.

As the printout becomes available, results should be noted with the subject's name and attached to the requisition form. When the run is finished, press "Open" and retrieve the cassette tray from the *CLA-1 Luminometer*.

**HITACHI**  
Inspire the Next

United States Office  
© Hitachi Chemical Diagnostics, Inc.  
630 Clyde Court  
Mountain View, CA 94043  
Tel: 650 961 5501 or  
800 233 6278  
www.hcdiagnostics.com