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HITACHI CHEMICAL DIAGNOSTICS CLA[®] ALLERGY TEST: HELPING FAMILY PHYSICIANS PREVENT AND TREAT ALLERGIC AND IMMUNOLOGIC PROBLEMS

The sixth leading cause of chronic diseases, allergies—including Rhinitis, sinusitis, dermatitis, asthma, food allergy, and other allergic disorders—impact more than 50 million Americans.¹

The American Academy of Family Physicians (AAFP), noting the significant impact of these conditions on families, advises members to adopt an active preventive and therapeutic role with patients presenting with allergic and immunologic problems.²

Preventing and Treating Allergic and Immunologic Problems

Harold H. Hedges, III, M.D., Family Practitioner at the Little Rock Family Practice Clinic, and Susan P. Pollart, M.D., Associate Professor of Family Medicine at the University of Virginia Health System, in an AAFP CME program³ offer practice recommendations for family physicians:

- “Treat patients diagnosed as having allergic seasonal rhinitis with prophylactic medications (antihistamines and/or intranasal corticosteroids).
- Prescribe intranasal corticosteroids to control allergic rhinitis symptoms.
- Educate patients with allergic rhinitis about avoidance activities.
- Reserve immunotherapy for patients with allergic rhinitis for whom optimal avoidance measures and medication therapy are insufficient to control symptoms.”

Preventive and therapeutic treatment protocols for patients with allergic and immunologic conditions are also offered by The American Academy of Allergy, Asthma & Immunology (AAAAI).¹

A three-tier approach to preventive strategies for patients with allergic and immunologic problems includes:

- *Primary:* Block sensitization and development of the IgE-mediated response.
- *Secondary:* Block the expression of the disease, despite sensitization.
- *Tertiary:* Target control of factors that increase symptoms.



The CLA[®] Allergy Test (manufactured by Hitachi Chemical Diagnostics) is a cost effective, compact, and flexible system that—through one simple blood test—measures a patient’s reaction to many allergens.

Guidelines for management, of allergic and immunologic diseases, recommend physicians counsel patients on:

- Avoiding or minimizing exposure to allergens and irritants through environmental control.
- Using appropriate medication.
- Evaluating for allergen and immunotherapy.
- Educating the patient and appropriate caregiver(s).

Diagnosing Allergic/Immunologic Problems

Drs. Hedges and Pollart comment “that treatment guidelines often rely heavily on physician expertise and patient history—rather than evidence-based diagnostic criteria.”³

“The diagnostic algorithm for human allergic disorders (immediate or type 1 hypersensitivity) begins with an appropriate clinical history and physical examination,” according to findings of an AAAAI Ad Hoc Committee of the Practice, Diagnostics and Therapeutics Committee.⁴

Composed predominately of physicians, the AAAAI work group recommends that, “Once the medical, family and environmental histories identify a temporal association between allergic symptoms and allergen exposures, allergic disease may be suspected or confirmed, depending on the strength and

consistency of the findings. Most often, however, diagnosis of an allergic disorder requires confirmation by selected tests that are performed to verify the patient's production of specific IgE antibody."

The advent of today's improved in vitro blood tests for specific IgE allow primary care clinicians to approximate allergists in diagnostic precision.⁵ Family physicians, seeing a suspected allergic patient should consider testing for allergen-specific IgE to identify the specific course.⁶

In addition to confirming the diagnosis of allergy and immunologic conditions, differentiation of the particular allergens and immunologic disorder are required to design the optimal treatment protocol.

Offering an Easy and Safe Tool: Hitachi Chemical Diagnostics CLA® Allergy Test

The CLA® Allergy Test is an accurate, easy to use blood test for the primary diagnosis of allergic disorders. It offers physicians evidence leading to avoidance therapies, medication selection, and/or reduces the cost of inappropriate medications and referrals. Overall, patients receive a better understanding of their disease when their physician can explain it specifically.

CLA technology offers objective evidence-based diagnoses. Minimally invasive, CLA requires only a single blood sample. Physicians comment on their ability to quickly and safely diagnosis—and rapidly enable patients to start therapy.

Added-Benefits: Hitachi's Patented CLA® Pette and and CLA-1™ Luminometer

The CLA® Allergy Test (manufactured by Hitachi Chemical Diagnostics) is a cost effective, compact, and flexible system that—through one simple blood test—measures a patient's reaction to many allergens.

The CLA Pette is a small, plastic device designed to measure the severity of reaction for up to 36 different allergens. An extensive variety of allergens is available and testable from a single blood sample.

Panels include:

- Inhalant: Pollen, dust, mites, and other airborne allergens specific to the patient's geographic area.
- Food: Common food sensitivities, e.g., milk, tomatoes, soybeans, wheat.
- Combination: Mixture of common food sensitivities and inhalant allergens (up to 36 allergens).

The CLA Pette is comprised of 36 cellulose threads. Each thread contains a selected allergen. Serum from the patient's blood sample is aspirated into the CLA Pette. Allergic reactions are triggered when IgE-specific antibodies in the serum bind to allergens in the cellulose threads. The addition of reagents then produces different intensities of light—the intensity of the light reflects the severity of the allergen. Diagnostic findings are determined by loading the Pette into the CLA-1 Luminometer.

Hitachi Chemical Diagnostics CLA® Allergy Test

- Tests for 36 specific IgE results, including inhalants, foods, and/or combinations of them, using predetermined geographically or category-specific panels.
- Offers accurate test results with good correlation to skin testing and other in vitro allergy tests.⁷⁻¹⁰
- Consumes little workspace, requires little time, and is easy to use.
- Reimburses using CPT Code 86003 multiplied by the number of allergens per panel tested. Many insurers have generously incorporated these cost-saving screens into their coverage guidelines.⁴

Referral to an allergist or immunologist is advised for more comprehensive evaluations of some patients. In patients with strong positive histories of systemic reactions and/or anaphylaxis who

are found to have negative skin or in vitro testing for IgE antibody, the reactions may be non-immunologically mediated or the quality of the materials available for testing may be suspect. Such a patient should be considered at risk for further reactions. Treatment options should be reviewed and a comprehensive assessment is warranted.

About Hitachi Chemical Diagnostics

Hitachi Chemical Diagnostics collaborates with industry leaders to offer solutions to health, and safety. Committed to furthering medical diagnostics, Hitachi Chemical Diagnostics is working on development of automated allergy diagnostic systems to help family physicians fulfill their goal of assuming a key preventive and therapeutic role in treatment of patients with allergic and immunologic conditions. ♦

To Learn More

For more information call 1-800-233-6278, or visit the company Web site at www.hcdiagnostics.com.

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