

Correspondence

Moderately complex US Food and Drug Administration–cleared method for human IgE antibody serology

To the Editor:

Recently, Hamilton and Williams¹ published a primer on specific IgE testing on behalf of the American Academy of Allergy, Asthma & Immunology, and the American College of Allergy, Asthma and Immunology. Although the authors state that their communication is inclusive of all clinically available tests of specific IgE, there is a widely used methodology that they fail to identify.

The authors on page 34 refer to “the 3 clinically used FDA-cleared assays” and seem to be referring to those assays providing IgE quantitation. However, the article includes a newly available IgE test, the ImmunoCAP Rapid (formerly Pharmacia, Kalamazoo, Mich), and a similar *in vitro* device is not mentioned. In fairness considering the stated purpose of the article to inform practicing clinicians of those US Food and Drug Administration (FDA)–cleared test systems currently available, this omission should be rectified.

The chemiluminescent assay (CLA) Allergy test by Hitachi Chemical Diagnostics (Mountain View, Calif) is an FDA-cleared moderately complex allergen-specific IgE test adherent to the same stringent standards and controls that the authors address. It has been continuously available and marketed in the United States since the FDA cleared the first product of MAST Immunosystems in 1983 using Pharmacia’s system as the substantially equivalent device.² Newer FDA-cleared products have been added in a continual process to advance and improve the product.³ Like the newly cleared ImmunoCAP Rapid, the CLA methodology developed in accordance with Clinical Laboratory Standards Institute guidelines uses a small sample to provide individual semiquantitative allergen-specific test results. Currently in the United States alone, hundreds of physician office laboratories use this system. The CLA method offers results for nearly 100 FDA-cleared allergens. As a moderately complex *in vitro* diagnostic test, it can be used and reported only through a Clinical Laboratories Improvement Amendment-certified clinical laboratory. Inherent in the Clinical Laboratories Improvement Amendment certification is the requirement for participation in outside

proficiency assessment. The Hitachi Chemical Diagnostics CLA test is among those methodologies listed in the example program mentioned by the authors, “the SE survey conducted by the College of American Pathologists.”¹

An added line to Table I is provided that details specific characteristics of the CLA Allergy method.

The authors have a well-crafted report of *in vitro* allergen-specific IgE methodologies currently available to practicing clinicians. In reviewing the FDA Web site for all cleared *in vitro* diagnostic tests, the only currently used test that appears to have been overlooked is CLA Allergy. THABESTIgE⁴ method is listed in CAP proficiency testing,⁵ but relevant contact information is elusive, and there is only a single 510(K) clearance issued in 1986.

This correspondence is intended to correct an oversight by including the CLA methodology. I have endeavored to provide this information in a clear and factual manner in accordance with the presentation of the other listed testing options without specific bias toward any available test method.

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Disclosure of potential conflict of interest: V. Saper is a part time consultant for Hitachi Chemical Diagnostics.

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TABLE I. Addition to the authors’ table entitled “Fundamental features of clinically used allergen-specific IgE antibody assays”

Name	Company	Solid-phase matrix	Enzyme-labeled detection antibody	Substrate*	Calibration system	Analytic sensitivity†
CLA	Hitachi Chemical Diagnostics, Inc	Cellulose thread	Horseradish peroxidase–labeled anti-IgE	3-aminophthalhydrazide	Factory-calibrated semiquantitation	Semiquantitative assay with 86% to 100% clinical concordance with another cleared IVD test

*The CLA is a chemiluminescent assay.

†Manufacturer-reported analytical sensitivity as cleared by the FDA.