

December 27, 1997

The Editor-in-Chief,
Jonathan Collin, MD
Townsend Letter for Doctors and Patients,
911 Tyler St.
Pt Townsend, WA 98368-6541

Dear Dr. Collin;

I read the article by Dr. Sheryl B. Miller and the editorial by Dr. Gaby concerning the use of ELISA testing for food sensitivities in the January issue with great interest. They both express concern regarding the promotion of this test for the following reasons:

1. Lack of intra-laboratory reproducibility.
2. Lack of documented clinical correlation with disease states.
3. Doubtfulness concerning the role of IgG food specific antibodies in the pathophysiology of adverse reactions to foods as IgG antibodies have been shown to play a blocking or protective role in many instances. Hence, there are a lot of false positives.
4. The likelihood that many adverse reactions to foods are not immunologically mediated but are pharmacologically mediated and thus not detectable through immunological assays.
5. That the observed reactivity may be due to contaminants in the food (such as bacteria or fungi) rather than the actual food itself.
6. The process of digestion alters the composition of the food; and, in many instances, it's allergenicity.

Recognizing these problems my laboratory sought the development of a test for adverse reactions to foods, food components, molds, chemicals and other substances, some fifteen years ago. It is called the ALCAT Test. Our approach involves the use of a cellular test employing a specially designed hematology analyzer and innovative reagents, capable of measuring subtle changes in the size, and the count, of white blood cells, and agglutination of platelets, when the whole blood is challenged, in vitro, by a battery of test substances, usually food extracts. Samples from the same blood specimen, identically treated, but without the test reagent, serve as controls. (This method has been awarded three US and several foreign patents.)

As such this test overcomes almost all of the concerns expressed by Doctors Miller and Gaby. Food sensitivity is clearly mediated by a multitude of pathogenic mechanisms, both immunologic and non-immunologic. Peter Fell, MD, of Oxford, UK, a clinical pharmacologist who has taken up the practice of allergy and food sensitivity after serving as the medical director of a major pharmaceutical company, has investigated our test and has found that it is capable of identifying adverse reactions to the purified chemicals that naturally occur in foods, in some cases the same ones mentioned by Dr. Gaby, in a manner that is reproducible and clinically relevant. In his view allergen induced alteration in the size and/or number of leukocytes appears to reflect a final common pathway of several mechanisms; immunologic, pharmacological and toxic. Working in conjunction with Dr. Jonathan Brostoff, at the Middlesex Hospital. Med. School in London, Fell also reported an 83.4% correlation with our test results and double blind oral challenges with foods. Lene Hoj, an allergist in

Copenhagen, and probably the first investigator to publish a double blind trial linking asthma to food sensitivity, reported a 96% correlation with our test and double blind, placebo controlled oral challenges with food additives. The test is slightly more specific than it is sensitive; hence, there are very few false positive responses.

An important distinction between our test and the ELISA, or other immuno-assays for foods, is that ours is carried out using whole blood, within a time frame where the cellular elements, as well as serum factors, are still viable. This renders the test more like ex vivo test which, among other things, means that the processing of the food extracts includes interaction with the lymphocytes which contain all of the enzymes and substrates that are involved in hepatic biotransformation. Years of development of manufacturing processes and instrumentation have rendered an assay, that as a biological assay, is highly reproducible. Looking at outcomes of whether to eliminate or not to eliminate a food (or food additive) is usually about 90% reproduced.

The limitations of the test are that the blood must be analyzed within 28 hours from blood draw and, at least for the present, the food extracts that are used in the test, for good or for bad, come from the same manufacturers that supply other laboratories.

Whereas I agree with both doctors' conclusion that the ELISA test is not of value for food sensitivities I would hope that the ALCAT Test would not be lumped together with ELISA and that it is judged independently, on its own merits. This test is moderately priced, and has been instrumental in unraveling complicated medical problems on so many occasions it would be quite sad if it were over looked or confused with the ELISA test.

Reprints of the studies I have mentioned are available at no cost to anyone who requests them.

Sincerely,

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