

The Flaw In Cytotoxic Testing:

There's No Proof It Works

by Richard C. Thompson

Cytotoxic testing is touted as a way of tracking down and curing ills by on-the-spot testing of blood for food allergies. While the idea may sound plausible, there is no proof it works.

Yet such testing has been highly promoted. The promotions began in 1983 with newspaper ads that invited investors to get into the "profitable field" of allergy testing.

For an investment of about \$30,000 the promoters supply test kits and training and show the investor how to operate an allergy clinic. The investor purchases the kits, chooses the location, and provides clinic staff.

Ads were run in national newspapers, among them *The Wall Street Journal*. The ads said investors could get rich using "a scientific breakthrough that charts 245 food allergies simply and efficiently."

Within weeks, storefront clinics began appearing around the country and FDA began receiving inquiries from

the news media, consumers and health professionals.

But these ads to investors—and later ads by the operators themselves—misrepresent the nature of cytotoxic testing. It is not an accepted clinical procedure, and the significance of the test results, if any, has not been established.

The promoters also claim that only a business permit is required to operate a clinic and that cytotoxic testing is "nutritional analysis" and not subject to federal or state regulation. But they are mistaken. The food extracts used are biologics licensed by FDA; thus they are prescription drugs that can be ordered only by a physician. Using them in a blood test gives FDA added jurisdiction under medical device laws. And the clinics themselves may require licensing by state or local health authorities.

In cytotoxic testing, about 10 cubic centimeters (one test tube) of blood are taken from the patient. The white

CYTOTOXIC FOOD TESTS A NEW HEALTH APPROACH

Do you occasionally suffer from headaches, stomachaches, sinus problems, skin problems and rashes, overweight difficulties (even that last 10 lbs that won't come off), stress, fatigue, water retention or any combination of the above? Doctors and nutritionists say food may be the cause.

A new revolutionary nutritional blood test called CYTOTOXIC shows how an individual's system may react poorly to certain foods.

The CYTOTOXIC test is a detailed examination of food and chemical sensitivities. Results are determined by measuring the destruction of your white blood cells caused by exposure to these specific foods and chemicals. CYTOTOXIC means cell poisoning.

"I was feeling sluggish & awful until I applied the CYTOTOXIC test. Then within three days I felt an incredible increase in my energy level and mental attitude," one woman says. "I no longer get tired or moody and I'm back to a normal life."

The examples are numerous: Ed was 60 lbs overweight and had high blood pressure. Caroline was 20 lbs overweight & had continual sinus problems, headaches & swelling. Mike took aspirin daily for 18 years due to

chronic headaches. Ellen went through fits of depression, crying, and withdrawals without warning. All of these problems were eliminated after taking and applying the CYTOTOXIC Test.

The principle behind this exciting discovery is simple. Your blood is tested for its reaction to nearly 200 commonly eaten foods and additives. During this sophisticated test the behavior of your white blood cells with each individual food is observed under a microscope. When a food is compatible with your body, the blood cells stay active, healthy and alive when exposed to that food. If however, a food is causing inconsistencies, your white blood cells begin to wrinkle, crack, burst open and die.

If your white blood cells crack, burst open and die, your immune system is caused impairment and your white blood cells release a powerful & destructive enzyme. In short, the door is thereby opened to poor nutrition and a possible multitude of unpleasant ailments and symptoms.

Once the offending food substances are removed from your meals, healthy white blood cell activity resumes. The body is no longer expending its precious energies fighting substances it identifies as toxic, and begins to function more smoothly and harmoniously than before.

The Bio-Health CYTOTOXIC testing program is directed by a licensed physician and if you currently suffer from any health difficulties, this test is worth taking and may or may not be covered by your medical insurance. It is important to ask Bio-Health Centers for special assistance in this area.

Bio Health Centers of California conducts this specialized test all over the country and is sending a special nutritional team to the Seattle area on Wednesday evening, August 15, 1984 to conduct the CYTOTOXIC test for those who desire testing.

They are limited as to how many persons they can help, and reservations are mandatory. You may not be able to eat for 6 to 12 hours prior to the test so calling for instructions is advised. For more information, call Bio Health Centers CYTOTOXIC Department TOLL FREE at 1-800-821-6605 or at 1-714-898-0808.

This test is not currently approved by the FDA, or recognized by the American Academy of Allergists.

cells (leukocytes) are mixed with plasma and sterile water and placed on microscope slides, after each slide has been coated with the dried extract of a particular food. There are generally 200 slides representing 200 different foods. The reaction of the cells to the extracts is examined under a microscope. If the cells collapse, disintegrate or change shape (or the person examining them says they do), the patient is supposedly allergic to that particular food.

This evidence of food allergy is then used to explain a variety of symptoms patients may have or think they have. To correct this condition the clinic typically offers a "personalized diet program," devised by the clinic operator, that includes vitamins and minerals the clinic has for sale. Investors are told they should make even more money on these products than they do for the testing itself.

The claims made by operators of the clinics are not modest.

Cytotoxic testing will, says one, deliver you from asthma and arthritis; from canker sores, chronic cough and confusion; from diarrhea and depression; from heart palpitations and headaches; in fact, from 27 flaws in the human condition.

It can, says another, protect you against "the disasters linked to the food you eat . . ."

A third claim is simplicity itself: "Feeling bad? Try cytotoxic testing."

The list of conditions that promoters claim are related to food allergy also includes anxiety and acne; baldness, back pain and bedwetting; constipation, crying and conjunctivitis; eczema and fatigue; hearing loss; insomnia; learning disorders; obesity; rashes; and stomachache, stress and water retention.

Don't believe it. FDA, the National Institutes of Health, and the American Academy of Allergy and Immunology say there's no evidence it works.

The procedure is also known as Bryan's test, leukocyte antigen testing, and food sensitivity testing. But, by whatever name it is called, there's no evidence as yet that it tests for food allergies. There have been no controlled experiments showing that white cells shrink, shrivel and die when exposed to food substances to which a person is allergic. Until there are, the academy and the National Institute of Allergy and Infectious Diseases say cytotoxic testing "must be considered an experimental procedure" with no clinical uses.

The usual patient-doctor relationship doesn't exist in cytotoxic testing. Patients apparently are not seen or examined by a physician, yet use of allergenic extracts can be legally ordered only by a medical doctor.

There is also the question of whether clinic personnel are qualified to assess symptoms, read the microscope slides, and offer nutritional guidance. A technician takes blood from the patient, and lab personnel apply it to the slides. The results may be interpreted by a "nutritional counselor" working on commission who will then note the vitamins and minerals—available right there or next door—that the patient will need to correct this "allergic condition."

Cytotoxic testing is expensive, costing from \$200 to \$400 for the usual series, plus additional charges for the vitamins. Although ads imply this is covered by health insurance, the clinics require that the patients pay and then be reimbursed. Medical insurers are questioning the procedure, and the Health Care Financing Administration that funds Medicare intends to exclude cytotoxic testing from its coverage. HCFA says such testing "lacks evidence of clinical effectiveness and has no scientific rationale."

There are some 1,200 extracts of various substances prepared by licensed suppliers and approved by FDA for allergy skin tests. About one-fourth are food extracts, labeled and intended for certain uses. Cytotoxic testing is not one of those uses, and no manufacturer of these extracts has requested FDA approval to market for such use. Some clinics may be preparing their own food extracts or obtaining them from sources within the state where they are used, which makes them less readily subject to FDA regulation.

FDA is investigating cytotoxic clinics and promotions, which seem designed to operate outside the traditional practice of medicine. Meanwhile, the agency advises persons who believe they may have a food allergy to see a properly trained physician for a complete medical history, physical examination, and thorough diagnosis and proven treatment. ■

Richard C. Thompson is a member of FDA's publications staff.

DISCOVER YOUR FOOD ALLERGIES

The Cytotoxic Test \$195

"Cyto" Latin for cell and "Toxic" for poisoning, the Cytotoxic Test is a measure of your body's allergic sensitivities to over 400 foods, chemicals and additives. Sensitivities responsible for symptoms such as: difficulty losing weight, bloating after meals, migraine headaches and eczema to name but a few. At the Beverly Hills Health Center your cytotoxic test results are organized into a unique, easy to follow computerized program. A blood chemistry panel will also reveal such factors as hypoglycemia, cardio-vascular risk, cholesterol and triglyceride levels, underactive thyroid, liver function and many more. This specialized program is also designed to detect any Vitamin Deficiencies you may have. The doctor will then interpret all your results and make nutritional recommendations as part of your cytotoxic program.

For Further Information Call: 659-5787
THE BEVERLY HILLS HEALTH CENTER
121 N. SAN VICENTE BLVD., BEVERLY HILLS

— SPECIAL OFFER —

Ad at right is directed to investors and appeared in The Wall Street Journal; items on the facing page, below and on the following page were placed by the clinic operators and are directed to potential customers. The ad on the facing page is from the Aug. 8, 1984, Seattle Post-Intelligencer and includes an insertion by the newspaper that cytotoxic testing is not an approved or recognized procedure. Below is part of a full-page ad that appeared in the July 14, 1984, New York Times. Ad on following page is from the March 18, 1984, Los Angeles Times.

GET RICH!

BE FIRST in your area to open a very lucrative allergy testing center—an **ALL-CASH-UP-FRONT** money-maker which uses a scientific breakthrough—a blood test that charts 245 food allergies simply and efficiently. Not a franchise, but we train, support and assist you. \$30,000 capital outlay.* **ABSOLUTE PROOF** of marvelous earnings by visiting our successful operation at our corporate headquarters. Write or telephone:

NATIONAL ALLERGY CLINICS
405 N. BEDFORD DRIVE - SUITE 301
BEVERLY HILLS, CA 90210
TELEPHONE: (213) 859-0617
MR. BAILEY

*Plus some additional start-up costs.

If you suffer from any of these symptoms, you may be sensitive to the foods you eat.

- | | | |
|---------------------------------------|---|--|
| <input type="checkbox"/> STRESS | <input type="checkbox"/> SINUS PROBLEMS | <input type="checkbox"/> SNEEZING |
| <input type="checkbox"/> HEADACHES | <input type="checkbox"/> CHRONIC COUGH | <input type="checkbox"/> ITCHING |
| <input type="checkbox"/> NAUSEA | <input type="checkbox"/> BACKACHE | <input type="checkbox"/> CONSTIPATION |
| <input type="checkbox"/> RASHES | <input type="checkbox"/> HYPERACTIVITY | <input type="checkbox"/> DIARRHEA |
| <input type="checkbox"/> CANKER SORES | <input type="checkbox"/> HEART PALPITATIONS | <input type="checkbox"/> SYMPTOMS OF COLITIS |
| <input type="checkbox"/> INSOMNIA | <input type="checkbox"/> DEPRESSION | <input type="checkbox"/> CRYING JAGS |
| <input type="checkbox"/> ARTHRITIS | <input type="checkbox"/> WEIGHT GAIN | <input type="checkbox"/> IRRITABILITY |
| <input type="checkbox"/> FATIGUE | <input type="checkbox"/> HOARSENESS | <input type="checkbox"/> CONFUSION |
| <input type="checkbox"/> ASTHMA | <input type="checkbox"/> SORE THROAT | <input type="checkbox"/> MUSCLE ACHES |

Even good foods could be bad for you.

The trouble is that you probably don't even know which foods you're allergic to. So you make your allergies worse by "feeding" them. In fact, the foods that can be toxic to your system are the same foods that you were taught were "good for you."

You're probably allergic to at least 3 foods on this list.

- | | | |
|----------------------------------|------------------------------------|-------------------------------------|
| <input type="checkbox"/> MEAT | <input type="checkbox"/> WINE | <input type="checkbox"/> EGGS |
| <input type="checkbox"/> FISH | <input type="checkbox"/> LIQUOR | <input type="checkbox"/> FRUIT |
| <input type="checkbox"/> CHICKEN | <input type="checkbox"/> CHOCOLATE | <input type="checkbox"/> VEGETABLES |
| <input type="checkbox"/> WHEAT | <input type="checkbox"/> SUGAR | <input type="checkbox"/> COFFEE |
| <input type="checkbox"/> BREAD | <input type="checkbox"/> MILK | <input type="checkbox"/> TEA |
| <input type="checkbox"/> BEER | <input type="checkbox"/> CHEESE | <input type="checkbox"/> SODA |

seminars held by a culinary expert, where you'll learn to prepare delectable and satisfying meals especially designed to aid you in your program.

Lose Weight Easily.

Even if you've tried to lose weight before and couldn't, you'll find it easier after our diagnosis. At The New York Metabolic Group we found that food allergies can cause swelling and water retention, making it impossible for some people to lose weight. So whether you have to lose a little or a lot, The New York Metabolic Group can help.

Enjoy the benefits of a personalized vitamin program.

You will be seen by a physician and a staff member trained in nutrition who will devise a vitamin and mineral regime that will properly supplement and fortify the diet that is developed based on your food intolerances.

Noticeable results within weeks.

When you go on your personalized program you'll feel better within weeks. Some people tell us they feel the difference within days. You will experience more restful sleep, increased energy, easier digestion, less irritability and an overall heightened sense of well being.

So call The New York Metabolic Group today for your appointment or a free brochure.

And find out if the foods you love, love you.

The New York Metabolic Group

Specialists in modern food allergy testing & treatment. (212) 486-1590

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^{FDA} CONSUMER

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