ALLERGY SOCIETY OF SOUTH AFRICA

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POSITION STATEMENT

ALCAT and IgG Allergy & Intolerance Tests

We are constantly consulted by colleagues, health funders and practitioners about the reliability and appropriateness of the ALCAT and IgG food allergy tests for patients with suspected allergies and other disorders. We would like to provide the following information to the readership of the journal and to the public.

The manufacturers and suppliers of ALCAT and the IgG test claim that the tests have diagnostic value in identifying substances responsible for allergic and intolerance reactions. These tests are being marketed directly to the public and health professionals, claiming to be more effective than traditional skin prick tests or serum specific IgE tests, particularly for delayed allergic reactions.

The manufacturers of the ALCAT test argue that orthodox allergy practice does not recognize delayed allergic reactions, when in fact these reactions are universally acknowledged to play a role in up to 30% of the spectrum of allergic reactions!

To date neither ALCAT nor IgG has been shown to have any predictive value in the diagnosis of allergy or intolerances.

This is supported by a recent document released by the Advertising Standards Authority (UK) reporting that following complaints relating to advertising statements, the manufacturers of the IgG food test have had to withdraw 13 claims for efficacy/predictability of the test from their website.[i]

The ALCAT test measures cellular swelling or cell lysis when cells are exposed to test substances (e.g. foods) in vitro. The manufactures argue that the test is predictive for assessing and diagnosing a variety of conditions such as: migraine, headaches, ADD/ADHD, autism, insomnia, depression, anxiety, bed wetting, allergies, hay fever; asthma, post nasal drip, chronic sinusitis, irritable bowel syndrome (IBS), inflammatory bowel disease (Crohn's disease, ulcerative colitis etc) acne, eczema, psoriasis, urticaria, Candida, autoimmune diseases (Hashimoto's thyroiditis rheumatoid arthritis, lupus, multiple sclerosis), fibromyalgia, ME – yuppie flu, metabolic syndrome, obesity,

infertility , gastro oesophageal reflux, poor memory, unexplained chronic fatigue and weight loss. They claim that the test is “The world’s gold standard” and “. . . recently cited as the world's number 1 food sensitivity test”.

The ALCAT was evaluated in the Allergy Unit at Groote Schuur Hospital in 1994 by the University of Cape Town Respiratory Unit, the University of Cape Town Gastrointestinal Unit and the Allergy Clinic at the Red Cross Children’s Hospital in patients with asthma, eczema and irritable bowel syndrome. The ALCAT’s predictive value was found to be extremely poor and not of benefit in identifying the trigger of the patient’s symptoms. There was no improvement of the patients who were followed up by a doctor and a dietician, using the diets recommended by these tests.[ii, iii, iv]

Consensus statements released by Allergy Societies throughout the world (including the representative body of all European allergy societies, The European Academy of Allergy and Immunology (EAACI)) do not recommend the use of this test in the evaluation of acute or delayed allergic or intolerance reactions.[v, vi, vii]

The American Academy of Allergy Asthma and Immunology (AAAAI) states: ". . . no evidence in the recent literature that convincingly changes the conclusions about the cytotoxicity test (ALCAT) in the evaluation of possible allergic diseases".[viii] The Allergy Society of South African (ALLSA) published a consensus statement in the South African Medical Journal in 1992.[ix] This position statement was subsequently reviewed and a second position paper published in Current Allergy and Clinical Immunology (the ALLSA journal) in 1994. The Australasian Society of Clinical Immunology and Allergy (ASCIA) states: "It is extremely important to note that there is no place in the diagnosis of milk allergy for unproven tests such as Vega testing, kinesiology, cytotoxic food testing, hair analysis or ALCAT tests."[x]

The British Society for Allergy and Clinical Immunology position is: "The Nutron and ALCAT tests (also known as leucocytotoxic tests) measure cellular changes in the blood after introduction of various food allergens. These tests had a poor reliability for diagnosing allergies when they were subjected to clinical trials according to the European Academy for Allergology and Clinical Immunology."[xi] The World Allergy Organisation and GLORIA (Global Resources in Allergy) have recently published their standpoint on the ALCAT: "Tests with no diagnostic value for any disease under any circumstance (not based on sound scientific principles): Cytotoxic test, Antigen leukocyte cellular antibody test (ALCAT)".[xii]

These viewpoints have been reiterated in recent international reviews of allergy diagnostic tests.[xiii, xiv, xv, xvi, xvii, xviii, xix]

It is significant that there are also no peer-reviewed publications or any reasonable studies to support a diagnostic value for any of the non-allergy related conditions for which ALCAT claims to be of value. It is also significant that not a single non-allergy clinical society worldwide has supported the use of the ALCAT for any of the conditions for which ALCAT claims this test has diagnostic value.

The second test marketed with insufficient documentation is the IgG test for food allergies. Specific IgE determination and its diagnostic value have been documented for over three decades in being specific for allergic disorders. Although IgG does play a role in the allergic response, there is no evidence to suggest that it has a diagnostic value in predicting food allergens or other substances that may be affecting individuals.[xvi] The IgG test is also marketed as effective in predicting foods implicated in Attention Deficit Disorder and obesity. There is no published evidence for these claims.

Wüthrich states: "Although some papers suggest a possible pathogenetic role of IgG, IgG4 antibody, no correlation was found between the outcome of Double Blind Placebo Controlled Food Challenge (DBPCFC) and the levels of either food-specific IgG or IgG4, nor was any difference seen between patients and controls. The levels of these and other food-specific immunoglobulins of non-IgE isotype reflect the intake of food in the individual and may thus be a normal and harmless finding."[xix] Other authors have similarly concluded that strong IgG responses have been demonstrated to be a normal physiological response to certain proteins that are frequently ingested under normal circumstances, and are commonly detectable in healthy adult patients and children, independent of the presence or absence of food-related symptoms.[xx, xxi, xxii]

The Australian Society of Allergology and Clinical Immunology (ASCIA) Position Statement: Unorthodox Techniques for the Diagnosis and Treatment of Allergy, Asthma and Immune Disorders summarises the evidence for IgG in the diagnosis for food sensitivity/allergy: "IgG antibodies to food are commonly detectable in healthy adult patients and children, independent of the presence or absence of food-related symptoms. There is no credible evidence that measuring IgG antibodies is useful for diagnosing food allergy or intolerance, nor that IgG antibodies cause symptoms. The exception is that gliadin IgG antibodies are sometimes useful in monitoring adherence to a gluten-free diet in patients with histologically confirmed coeliac disease."[xxiii]

Enrique et al[21]. states "We could even foresee future assays for specific IgG to foods as predictive of clinical tolerance in some disorders." For example, in IgE-mediated food allergy, elevated levels of IgG4 to foods have been correlated with the development of clinical tolerance, and not with worsening of clinical food allergy. This is demonstrated in an oral immunotherapy trial of hazelnut allergic individuals in whom increases in hazelnut-specific IgG4 occurred following the onset of tolerance to hazelnut.[xxii] In fact the exact role of IgG in immune disorders is still unknown. Teuber and Beyer note "[The role of IgG] is certainly a question for further research and emphasizes that it is far too early to encourage patients or insurers to spend money on blood test panels that are suited for research, and not clinical applications at this time."[xxiv]

It is disconcerting that the marketers of the IgG substantiate the use of their tests with studies which actually argue against the use of the test.[xxv]

In our opinion it is wrong to be marketing tests with little scientific validity. Both the ALCAT and IgG tests for "panels" of 20-30 allergens, costing patients up to R3,500. We have first hand

knowledge of patients who have been placed in financially compromising situations having paid for such tests with no relief of their conditions.

Furthermore, testing so many (up to 100) foodstuffs without obtaining a history of possible triggers or personal exposure to foods in the "fixed" panels is neither economical nor useful for diagnosis. The laboratories do not take into consideration the patient's history when doing such tests. As a result, these unproven techniques lead to misleading advice or treatments, and their use is thus not evidence based and does not help patients. Isolated claims for "success" in occasional patients by the manufacturers may be related to other factors and should be substantiated by double blind controlled challenge tests using scientific methodology.[xix] Inappropriate use of food allergy testing (or misinterpretation of results) in patients with inhalant allergy, for example, may lead to inappropriate and unnecessary dietary restrictions, with particular nutritional implications in children.[22]

We would therefore caution patients and doctors to be fully informed of the sensitivity and specificity of such testing, and to consider the evidence when contemplating such tests.

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[v] European Academy of Allergology and Clinical Immunology: Sections-Interest Groups - Allergy Diagnosis - Controversial diagnostic tests. http://www.eaaci.net/site/content.php?l1=91&sel=323 (06 November 2007)

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[vii] Position Paper: Controversial aspects of adverse reactions to food. EAACI Adverse Reactions to Food Subcommittee. http://www.eaaci.net/site/Adverse%20reactions%20to%20food.pdf (06 November 2007)

[viii] American Academy of Allergy Asthma & Immunology: Allergy & Asthma Disease Management Center – Allergy Testing. http://www.aaaai.org/aadmc/ate/allergytesting.html. (06 November 2007)

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[x] Australasian Society of Clinical Immunology and Allergy: Cow's Milk (dairy) allergy. http://www.medeserv.com.au/ascia/aer/infobulletins/hp_allergy_milk.htm (06 November 2007)

[xi] MedicDirect: Allergy Testing. http://www.medicdirect.co.uk/site_guide/default.ihtml?step=4&pid=2458 (06 November 2007)

[xii] Global Resources In Allergy (GLORIA™) – The Diagnosis of Allergic Diseases. http://www.3bel.dote.hu/oktatas2007/eload2007ang/Nekam%20TOK%20eloadas%20Allergy.ppt (06 November 2007)

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