

Hi Dr Steinman

Thanks for that excellent advice. I agree – the purpose of this trial can ONLY be to evaluate the reproducibility of the ALCAT Test

I was thinking along the same lines – a small 10 patient trial, and then subsequent trials to build further upon the clinical evidence of reproducibility that this offers

Initially I am going to take the first 10 test subjects that come along – I want to get this done as a matter of urgency – and then I will do as you say, set up trials according to their main presenting complaint / reason to test

Roger is in India at this time and although he is aware of our contact, I have no other directive from him except to wait until he returns to the US. I have no doubt Roger will support us fully in our endeavours to satisfy our critics. He was very keen to do this in January after he spoke with you, but we just did not get around to it. Thanks to you (meant sincerely!!) this project has become urgent, so I will not rest until we have this initial 10 patient trial under our belts

We are not that busy at this time, so I reckon we should have our answer within a month or so. I would like your help with further trials once this one has shown reproducibility, and I hope to gain your support after our effort has confirmed reproducibility. To date other countries have performed all of the recent trials (last 10+ years) and I would like RSA to come to the party, and I have no expertise in this area whatsoever, so I will need your help when you come to regard this test as a very real diagnostic and therapeutic adjunct to health. Every one I know thinks I am an eternal optimist!!

I have decided that we will withhold or blind the patient details to the laboratory technician on the first test, and to everyone but me on the second....I have to do the venesection, and record actual details I guess

If you can think of anything else that we should do to increase the value of this trial further, please let me know. Thanks again for your time and counsel

Regards

John

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The ALCAT Test - the world renowned and FDA approved blood test , unique to your immune biochemistry, that identifies your food intolerances and sensitivities (or delayed food allergies). ALCAT, a potent tool for treating weight loss, arthritis, asthma, eczema, IBS, migraines, fatigue, skin conditions, ADD and various other problems.

From: Dr Harris Steinman
Sent: 20 May 2007 08:27 PM
To: John Pridgeon
Subject: Re[4]: FW: ALCAT Test

Hi John,

Ten is not a definitive number - one would need about 20 or more for good stats. My thinking was 10 would give some indication, i.e., if not reproducible or high enough, you have one outcome. If good, then need to extend the number to around 20. Suggest selecting those with similar conditions, i.e., IBS rather than a mix of IBS, allergy, etc. The other point that is very important is to appreciate that any publication will need to expressly state that this is simply a study on reproducibility of the test and no clinical outcome or PV (predictive value) or sensitivity or specificity can be claimed- a clinical study will need to be done to evaluate these parameters. Of course you could ask Roger to subsidise or sponsor this - if he refuses, be afraid, be very afraid! I know other reproducibility studies have been done, but not with a 1-2 day separation. If he believes this type of reproducibility is possible, I would think that he would be prepared to sponsor this.

Harris

***** REPLY SEPARATOR *****

On 19/05/2007 at 11:29 AM John Pridgeon wrote:

Hi Dr Steinman

That sounds wonderful!!

I am going to get to work on this right away

I will get 10 patients who want to do the ALCAT Test and repeat the test 2-3 days later

That way we will only have to pay for half of the trial these things are expensive!!

Please help by adding any additional measures you think might be relevant, you are used to developing protocols, so that this might be considered by anyone as being a useful and proper trial

Thanks again for your input it is most appreciated. This indeed is what we had in mind in January

Have a great weekend

Regards

John Pridgeon

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From: Dr Harris Steinman
 Sent: 18 May 2007 02:37 PM
 To: John Pridgeon
 Subject: Re[2]: FW: ALCAT Test

Hi John,

You obviously believe in your product. Therefore to substantiate this belief, I suggest a small trial of say 5-10 individuals, where bloods are drawn and checked blindly 1-2 days apart - for reproducibility, not clinical effect (which would be a substantial trial).

This is one of the "gold standards" as opposed to the checking reproducibility the same day. The results, good or bad, we will submit for publication in a reputable journal.

Regards,
 Harris

***** REPLY SEPARATOR *****

On 18/05/2007 at 07:08 AM John Pridgeon wrote:

Hi again Dr Steinman

Thanks again for your time and trouble

I realise now that you are genuinely concerned about the validity of the ALCAT Test, and that your involvement here does not have any less honourable origins

I will do everything I can to convince you that all is well with this test, and to show you that it indeed is the world leader in food sensitivity testing

For myself, I am the medical director of ALCAT SA, not for personal gain, but because I believe emphatically in what it does. I have quite a lot of personal experience with the results of the test (1997-9 and since we started in August last year) and can report a significant success (in excess of 90% of patients were satisfied that they got their moneys worth, and would do the test again, and many people are enjoying better health than they have in years) this time around, and when I used it 8-10 years ago certainly the feedback is very seldom negative and generally the patients are very grateful, so SOMETHING positive is happening. The trick is to convert this to tangible and acceptable medical evidence

Like you I am a scientist, and the relative paucity of clinical studies **is** a big stumbling block for me. I have a number of pathologist friends in Natal who are sceptical, like you are. It is a point of view I accept, and my challenge is to provide reasonable evidence to win all you sceptics over..There ARE ongoing trials that I will be getting hold of, and will forward these to you in due course. In addition, anything that has happened in the last few years will be forwarded to you

I know that while you are a formidable enemy, you will also be a great ally

I will be trying to convert you to be the latter

So, here is to our working together in time to come, the onus of bringing that happy state of affairs about rests on my shoulders, and those of Cell Science Systems. In the meantime I intend to remove your name from our website at the first opportunity, and will also speak to Ulrike Wade, the Cape town GP, to let her know of our communications

Again, I ask that you communicate at all times directly with me, and remind you that I will be in Cape Town on the 29th of next month should you wish to meet

Have a great weekend! Mine will be.the Blue Bulls are going to get hammered!

Regards

John

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From: Dr Harris Steinman
Sent: 17 May 2007 06:57 PM
To: John Pridgeon
Subject: Re: FW: ALCAT Test

Hi John,

Yes, your email has reached me.

I suggest that you offer to do a reproducibility study to the relevant Excom members of ALLSA. This is not a test done on the same day on the same blood, but to repeat a blood sample on the same patient a day or two later. If you are able to get a high reproducibility, they may accept some of your bona fides. I do know that they take very seriously the status of journals in which research is published in - many journals out there are not peer reviewed, are not authoritative, or are not strictly scientifically based, and therefore for ALCAT to be taken seriously, research needs to have been published in authoritative journals.

I do not have the contact details of Prof. Brostoff, Dr Fell or Prof. Connie Katelaris. If Prof. Brostoff or Dr. Fell are still using the ALCAT then Roger should have no difficulty giving you their details. As I mentioned to you, Prof. Brostoff stated to me some years ago that they had stopped using the ALCAT routinely as it did not appear routinely effective, or words to that effect. I do not know what the present status is. According to Pubmed, Prof. Katelaris's contact details are: Katelaris CH, Allergy and Immunology

Services, Westmead Specialist Medical Centre, Sydney, NSW, Australia.
chk@allergyimmunol.com.au. I re-iterate, I am somewhat astounded that Roger did not inform you that we had conducted three large studies (IBS, Asthma, Eczema) with extremely poor results, and also, had not informed you about Prof. Katelaris's large study in Australia, nor on the consensus statements of a number of Allergy Societies around the world.

The author who wrote a consensus statement for the European Academy of Allergy and Immunology (EAACI), is Bindslev-Jensen C, Department of Dermatology and Allergy Center, Odense University Hospital, DK 5000 Odense C, Denmark. Carsten.Bindslev-Jensen@ouh.fyys-amt.dk. Roger was scathing regarding this chap, but considering that he still heads the Dermatology group of EAACI, he clearly is still highly regarded. Here is their standpoint: <http://www.eaaci.net/site/content.php?11=91&sel=323> An overview position of EAACI is also presented in this publication: Ortolani, C.; Bruijnzeel-Koomen, C.; Bengtsson, U.; Bindslev-Jensen, C.; Bjorksten, B.; Host, A.; Ispano, M.; Jarish, R.; Madsen, C.; Nekam, K.; Paganelli, R.; Poulsen, L. K.; Wuthrich, B. Controversial aspects of adverse reactions to food. *Allergy*. 54(1):27-45, January 1999.

Department of Allergology and Clinical Immunology, Niguarda Ca' Granda Hospital, Milan, Italy, Department of Dermatology, Academic Hospital, Utrecht, The Netherlands, Allergy Centre, Sahlgrenska University Hospital, Gvteborg, Sweden, Department of Dermatology, Odense University Hospital, Odense, Denmark, Department of Paediatrics, University Hospital, Linköping, Sweden, Department of Paediatrics, Odense University Hospital, Odense, Denmark, Dermatologic and Pediatric Allergy Clinic, Vienna, Austria, Institute of Toxicology, National Food Agency of Denmark, Department of Allergy and Clinical Immunology, National Institute of Rheumatology and Physiotherapy, Budapest, Hungary, Department of Clinical Medicine, University La Sapienza, Rome, Italy, Laboratory of Medical Allergology, National University Hospital, Copenhagen, Denmark, Allergy Unit, Department of Dermatology, University Hospital, Zurich, Switzerland. Also available here: <http://www.eaaci.net/site/Adverse%20reactions%20to%20food.pdf>

The AAAAI - American Academy of Allergy Asthma and Immunology standpoint is here: <http://www.aaaai.org/aadmc/ate/allergytesting.html> ("no evidence in the recent literature that convincingly changes the conclusions about the cytotoxicity test (Alcat) in the evaluation of possible allergic diseases" This and the European opinion is reported in this document: Unproved diagnostic and therapeutic approaches to food allergy and intolerance. *Current Opinion in Allergy & Clinical Immunology*. 3(3):217-221, June 2003. Teuber, Suzanne S. a,b; Porch-Curren, Cristina a

The South African Allergy Society position was published in the SAMJ : S Afr Med J. 1992 Apr 4;81(7):384. The ALCAT test-inappropriate in testing for food allergy in clinical practice. Potter PC, Mullineux J, Weinberg EG, Haus M, Ireland P, Buys C, Motala C. It was subsequently reviewed and a second position paper published in the journal, *Allergy & Clinical Immunology* (which is not available on the Web but through the ALLSA resource office). As far as I know, their position has not changed. Abstracts of a congress held in October 1994 (VOL.7 NO.3 OCTOBER 1994) Lack of correlation between self-reported food intolerance, food challenge testing and results of the ALCAT system in chronic adult asthmatics. A. Pitt, E.D. Bateman, H. Steinman, P.C. Potter.

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."

http://www.medeserv.com.au/ascia/aer/infobulletins/hp_allergy_milk.htm

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."

http://www.bbc.co.uk/health/conditions/allergies/testing_index.shtml

The World Allergy Organisation and GLORIA (Global Resources in Allergy)

(www.worldallergy.com) 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)" www.3bel.dote.hu/oktatas2007/eload2007ang/Nekam%20TOK%20eloadas%20Allergy.ppt

1.

Sincerely,

Harris

***** REPLY SEPARATOR *****

On 17/05/2007 at 04:24 PM John Pridgeon wrote:

Hopefully this reaches you without being returned

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From: John Pridgeon [mailto:johnpridgeon@mweb.co.za]
Sent: 17 May 2007 03:12 PM
To: 'info@factssa.com'
Cc: Harris Steinman (harris@factssa.co.za)
Subject: FW: ALCAT Test

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From: John Pridgeon [mailto:johnpridgeon@mweb.co.za]
 Sent: 17 May 2007 02:04 PM
 To: Harris Steinman
 Cc: Mark Coppin; Kevin Garrity; Samy Puccio; RDD7474@aol.com
 Subject: ALCAT Test

Hi Dr Steinman

Thanks for your time on the phone today, I appreciate it. You obviously take your job as a self appointed quackery watchdog very seriously!

As I mentioned we are not interested in unnecessary squabbles, but in making people well and I hope in time to improve your opinion of what we do

I am in the process of gathering a lot of (more recent) information for you, the MCC, the NPG, ALLSA, the BHF and anyone else who needs to know about this test. We will fill in the gaps of the last 7 years for you, with the help of our American Principles and international ALCAT colleagues

My details are as follows:

Dr John Pridgeon

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I would ask that in future you communicate directly with me, or if I am not available, with Mr Mark Coppin, co-director of ALCATSA rather than my staff (they get confused and angry, and cannot know what I know about our business). You have his cell number

I am available to meet with you when I am in Cape Town next month (29th June) should you so wish

In the interim, I hope we will maintain a cordial and professional relationship at all times. My goals, like yours, are very simple to make people well

We will deal with your complaint to ALLSA about the claims we have made about the ALCAT Test, and I have no doubt that we will do this to everyone's satisfaction. Perhaps next time though, you will come directly to me with any misgivings, as now a lot of time must be spent by this authority following up your complaint, and by us substantiating our claims for our test. We are all busy enough, but perhaps by forcing our hand, you have in fact done us a huge favour

Do you have any contact details for Prof Brostoff, Dr Connie Catalans, and Dr Peter Feller?

Yours sincerely

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