



ELISA/ACT BIOTECHNOLOGIES LLC

14 Pidgeon Hill Drive, Suite 300 • Sterling, VA 20165

Phone: 800.553.5472 • Fax: 703.450.2981 • E-mail: clientservices@elisaact.com

ACCURACY AND PREDICTIVE VALUE OF LRA BY ELISA/ACT[®] TEST

We may share a concern that lab tests be both consistent and clinically meaningful. In developing the LRA by ELISA/ACT[®] system, we have gone to unusual lengths to assure that this is the case. To assure consistency, we have asked several questions:

1. If multiple samples are taken, how do results agree?
2. If the same person is measured weekly, how do results agree?
3. If the same sample is analyzed when drawn, after shipping, and after three days storage, how do results compare?

During the three years that we applied this test during development, we had 100+ opportunities to have **multiple samples** taken at the same time. Usually these have been analyzed without the technician knowing that they come from the same person. Results replicate with an R value of **>.999**. There are occasional differences where a strong reaction is read as a moderate, or a marginal moderate is read as non-reactive. Otherwise, results are interchangeable.

During development, we tested more than 3,000 different subjects. This unusually large number of people reflects our commitment to a clinical service we stand by, and in which you can have confidence for your patients. When the same person is **measured weekly** (sometimes for months at a time, including myself as a regular control), results replicate with an R value of **.998**.

When the same sample is analyzed **fresh, after shipping, and after three days in the lab**, results agree, with an R value of **.998**. We spent two years shipping specimens during different seasons and to different parts of the country before we were confident that consistent results were obtained consistently. This procedure, partly because of the **one step ELISA** we've developed and partly because we are averaging results typically from $30 \pm 5 \times 10^3$ cells, is the most reproducible of any assay I've developed or in use in any clinical lab. You can hold us to our results. We have gone to unusual lengths to provide a test that is **clinically meaningful and predictive**. For example, in a group of 15 migraine headache subjects, complete remission has been achieved in 14 and provocation of migraines induced by blind food reintroduction. Interestingly, sometimes it takes more than one food concurrently to provoke response.

We are gratified that people often call to indicate how accurate the test is...especially in hard to identify or hidden offender foods. We also frequently receive calls that people who doubted the accuracy of our prediction, yet followed the program for 6 weeks or so, and when exposed to a suspect food, found strong symptomatic response. It seems that as immune system is actively in a repair phase that it is able (and often does) mount a stronger response to sensitized items. In the longer run, when repair is complete, the person is often able to reintroduce the items without symptom provocation.

We refer to the period of repair and avoidance as a window of opportunity for people during which they may be able to recover from years of deferred repair and immune system impairment, and after which they may have a reset immune system able to defend them without aggravated responses.

Please let us know your personal and clinical experience. We are interested in knowing the application and limitation of what we do. Your suggestions are actively sought.

Cordial good wishes to you, your staff, and patients,

Russell M. Jaffe

Russell Jaffe, MD PhD, FASCP

Fellow, Health Studies Collegium, and Director, ELISA/ACT Biotechnologies

