4 June Sent to Dr. Graham Hughes

Background

It is recognised that few diagnostic tests have specificity and sensitivity of 100%. The incidence of positive and negative results is dependent on individual variations in the concentration of the agent being measured relative to the extent of any pathological changes, and on the analytical performance of the test method. The use of screening tests to detect the presence of HIV antibodies has to be considered with these limitations in mind (1).

In view of the emotive issues which surround the diagnosis of AIDS, and the implications of the detection of a positive test to HIV antibodies, consideration of sensitivity and specificity is of particular importance. The appearance of biological false positives in individuals where there is a non-HIV associated disorder affecting the immune system, has been proposed (2,3). It is intended to compare a range of HIV test procedures as used within conventional clinical and laboratory settings to determine if they really are specific to the HIV antigen.

Methodology

Subjects

Thirty five subjects will provide specimens for testing. All of them need to be proven to have hyper gammaglobulinaemia:

Five HIV positive (proof of sero-positive status will be provided) individuals.
Five subjects with SLE
Five with candidiasis
Five individuals of African origin
Five alcoholics with chronic hepatitis C
Five multitransfused thalassaemia patients
Five oral drug users (cocaine & crack)

Absolute anonymity will be maintained and all specimens will be identified by test codes.

Measurements

Specimens will be sent to three laboratories so that three different ELISA HIV diagnostic test kits are evaluated. The laboratories will be asked to follow all their usual procedures for testing, interpretation, carrying out of further tests, and reporting. The same specimens will be resubmitted on a second occasion to check for reproducibility .

Interpretation

The results will be shown to immunologists, virologists and rheumatologists in Britain, Australia and Germany for a discussion of the test procedures and possible implication on issues of specificity, sensitivity and reproducibility.

References

1. Mortimer P (PHLS AIDS Diagnosis Working Group). Towards error-free HIV diagnosis: notes on laboratory practice. PHLS Microbiology Digest 9 (2): 61-64

2. Papadopulos-Eleopulos E, Turner VF, Papadimitriou JM. Is a positive Western blot proof of HIV infection? Bio/Technology 1993; 11: 696-707

3. Bermas BL, Petri M, Berzofsky JA, Waisman A, Shearer GM, Mozes E; Binding of Glycoprotein 120 Peptides from the HIV-1 Envelope by Autoantibodies in Mice with Experimentally Induced Systemic Lupus Erythematosus and in Patients with the Disease; AIDS Research and Human Retroviruses, Vol 10, Number 9, 1994; Mary Ann Liebert, Inc., Publishers.