DEPARTMENT OF HEALTH AND SOCIAL SECURITY
HANNIBAL HOUSE
ELEPHANT AND CASTLE LONDON SE1 6TE
TELEX 883669 TELEPHONE 01-703 6380 EXT

Your reference
Our reference

REGIONAL GENERAL MANAGERS
DISTRICT GENERAL MANAGERS
GENERAL MANAGERS, SPECIAL HEALTH AUTHORITIES FOR LONDON
POST GRADUATE TEACHING HOSPITALS
REGIONAL SCIENTIFIC OFFICERS
REGIONAL SUPPLIES OFFICER

REGIONAL MEDICAL OFFICERS)
DISTRICT MEDICAL OFFICER)For Information
REGIONAL TRANSFUSIONS DIRECTORS)

30 July 1985

EVALUATION OF SCREENING TEST KITS FOR HTLV III ANTIBODY

In his press release dated 27 June the Minister for Health announced that a test would be introduced to screen all blood given by blood donors for antibodies to the virus which causes AIDS. Arrangements would also be made for Sexually Transmitted Diseases clinics to provide a test for people who fear they may have been exposed to the disease.

The first stage of the evaluation of commercially available test kits has now been completed on behalf of DHSS by the Public Health Laboratory Service. The outcome of that evaluation has been considered by a panel of experts and a summary of their recommendations is attached. The National Blood Transfusion Service is now undertaking its own 2nd stage evaluation covering aspects peculiar to the use of kits in the blood donation screening context.

A more detailed account of the PHLS evaluation will be available on request from mid-August. Any enquiries should be addressed to **David Kennedy, room 325, 14 Russell Square, LONDON WC1B 5EP : Tel; [redacted]; or Peter Lister room 1004, Hannibal House, as above, Tel: [redacted].**

The Department has funded the PHLS to set up laboratory facilities to confirm the results of any blood donations found positive in the National Blood Transfusion Service, and to test the samples taken in STD clinics. However, recipients of this letter are asked to ensure that copies are passed to all those who might be involved in the supply and use of test kits.

Yours sincerely

M A HARRIS
Health Services Division

EVALUATION OF KITS FOR THE DETECTION OF THE ANTIBODY TO HUMAN T-CELL LYMPHOTROPIC VIRUS TYPE 3 (ANTI-HTLV III)

On behalf of the Department, the Virus Reference Laboratory of the Public Health Laboratory Service has evaluated five commercially-available kits for the detection of antibody to HTLV III, a marker of infection with the causative agent of the acquired immune deficiency syndrome (AIDS). The kits evaluated were those of Abbott Laboratories Limited, Electronucleonics Inc, Organon Teknika Ltd, Ortho Diagnostic Systems Ltd and Wellcome Diagnostics. The evaluation protocol, which was agreed with an expert working group and the manufacturers was designed to investigate the performance of the kits with sera for unselected blood donors; sera from groups of patients with AIDS or AIDS-related diseases and sera from groups of patients in which false positive results were a possibility. The performance of the kits using sera that had been heat-treated to inactivitate the virus was investigated, and they were also assessed for their ease of use. The evaluators were trained by the manufacturers' representatives and the kits were used in the way specified by the manufacturers in conjunction with the equipment supplied by them.

The results of the evaluation were considered by the expert working group and accordingly the following recommendations are made by the Department:

Kits suitable for use in diagnostic laboratories

Organon Teknika Ltd - Vironostika anti-HTLV 3 (indirect ELISA)

Wellcome Diagnostics - Wellcozyme anti-HTLV 3 (Competitive ELISA)

Ortho Diagnostic System Ltd - HTLV 3 BioEnzaBead (indirect ELISA)

These kits provided a clear distinction between positive and negative results, a low rate of false positive results and gave reliable results with heat-treated sera.

The other kits were less satisfactory. In particular, they produced an unacceptable number of equivocal results and generally gave unreliable results with heat-treated sera.

Kits appearing to be particularly suitable for use in Blood Transfusion Centres

Wellcome Diagnostics - Welcozyme anti-HTVL 3

Organon Teknika Ltd - Vironostika anti-HTLV 3

These two kits were especially easy to use. Wellcome's product which had the lowest number of procedural steps, could provide results in about two hours. Organon's kit, which had eight procedural steps, could provide results in 2 hours and 50 minutes. Both kits are being evaluated in the second stage of the project which is designed to investigate performance in large scale screening of blood donors and will be reported at a later date.

A full report of this first stage evaluation will be available from mid-August. Other commercial kits will be included in the evaluation as they become available.

Further information can be obtained from:

Mr D A Kennedy,
DHSS
Scientific and Technical Branch
Room 325
14 Russell Square
London WC1B 5EP
(Tel: 01-636 6811 Ext [redacted])

or

Mr P Lister
DHSS, Medical Division
Room 1004
Hannibal House
Elephant and Castle
London SE1 6TE
(Tel: 01-703 6380 Ext [redacted] or [redacted])