DEPARTMENT OF HEALTH AND SOCIAL SECURITY
HANNIBAL HOUSE
ELEPHANT AND CASTLE LONDON SE1 6TE
TELEPHONE 01-703 6380 ext.

Your reference
Our reference

REGIONAL GENERAL MANAGERS
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REGIONAL SCIENTIFIC OFFICERS
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REGIONAL MEDICAL OFFICERS)
DISTRICT MEDICAL OFFICERS) For information
REGIONAL TRANSFUSIONS DIRECTORS)

→ Aleen. to action as required.

1 August 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. In his letter of 30 July, Mr Hart advised Regional General Managers of the need to provide alternative testing arrangements, outside the National Blood Transfusion Service, for people who fear they may have been exposed to the virus.

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 later this month. Any enquiries should be addressed to David Kennedy, Room 325, 14 Russell Square, London WC1B 5EP: Tel GRO-C ; or Peter Lister, Room 1004 Hannibal House, as above, Tel: GRO-C ext GRO-C

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 Departments of Genito-Urinary Medicine or elsewhere. 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

GRO-C

M A HARRIS
Health Services Division

Copy to DMO
UKS + ADL.
Professor J.D. Williams
Professor S.I. Cohen.
Mr M. Cullingham
Dr P. Rodin
TPD 13/8

EVALUATION OF KITS FOR THE DETECTION OF THE ANTIBODY TO HUMAN T-CELL LYMPHOTROPIC VIRUS TYPE III (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 Ltd, 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 from 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 inactivate 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 equipment supplied by them.

The results of the evaluation were considerd by the expert working group and manufacturers were asked to comment. The following recommendations are made by the Department:

Kits most suitable for use in Diagnostic Laboratories

Organon Teknika Ltd - Vironostika anti-HTLV III (Indirect ELISA)

Ortho Diagnostic Systems Ltd - HTLV III BioEnzaBead (Indirect ELISA)

Wellcome Diagnostics - Welcozyme anti-HTLV III (Competitive ELISA)

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

The other kits were less satisfactory. In particular, they produced an unacceptable number of apparently false positive results, and generally gave unreliable results with heat-treated sera. Abbott Laboratories has since emphasised that heat-treatment of sera before testing was not part of the company's standard operating procedure. Manufacturers made a number of comments which will be included in the full report.

Evaluation in Blood Transfusion Centres

The second stage of the evaluation is designed to investigate the performance of kits in large scale screening of blood donations. The expert working group considered that the results of the PHLS evaluation indicated that the following products were particularly suitable for use in Blood Transfusion Centres.

Organon Teknika Ltd - Vironostika anti-HTLV III

Wellcome Diagnostics - Wellcozyme anti-HTLV III

These kits were especially easy to use. Wellcome's product, which had five procedural steps (the lowest number), could provide results in 2 hours. Organon's kit, which had 8 procedural steps, could provide results in 2 hours and 50 minutes. These two kits are the first to be assessed on behalf of the DHSS in the second stage of the evaluation.

Further Information

A full report of the first stage evaluation will be available later in August, and the results of the second stage evaluation will be reported at a later date.

Further information can be obtained from:

Mr D A Kennedy
DHSS
Scientific and
Technical Branch
Room 325
14 Russell Square
London WC1B 5EP

or

Mr P Lister
DHSS, Medical Division
Room 1004
Hannibal House
Elephant and Castle
London SE1 6TE