FACSIMILE TRANSMISSION

From: Department of Health
Communicable Diseases Branch
Wellington House
133-155 Waterloo Road
London SE1 8UG

Date: 14 November 1996

For the attention of: Dr Angela Robinson

Address: National Blood Authority

Fax No: 01923 211031

Sender: **Dr Vicki King**

Tel: GRO-C

Fax No: **0171 972 4348**

Number of pages including this page: 4

MESSAGE

Please find attached final copies of letters which have been sent by fax and by Epinet today.

Carolyn - Please pass to Dr Flanagan.

Kit Evaluation Grp.
Under Launch - Biokits.

ALL DIRECTORS OF PUBLIC HEALTH

NO CASCADE REQUIRED

14 November 1996

BIOKIT BIOELISA HIV 1 + 2 EIA TEST

Dear Colleague,

I attach a letter sent today by the Chief Executive of MDA to diagnostic laboratories and blood transfusion services in relation to the above kit.

Expert advice is that there is no justification for retesting stored blood samples or recalling patients who may have been tested using this test kit. However, any individuals who are concerned about their HIV status should be offered a named confidential test in the normal way.

Any patients who want information on HIV/AIDS issues should contact the National AIDS Helpline on 0800 567 123 which is a free confidential 24 hour service.

SIR KENNETH CALMAN
Chief Medical Officer

Inquiries about this letter should be directed to Dr V King, Communicable Diseases Branch, Health Promotion Division, Wellington House, 133-155 Waterloo Road, London SE1 8UG , tel: GRO-C

P:\data\press\biokit.cmo

FOR ATTENTION OF CHIEF EXECUTIVES/DIRECTORS OF LABORATORIES AND THE BLOOD TRANSFUSION SERVICES

14 November 1996

BIOKIT BIOELISA HIV 1 + 2 EIA TEST KIT

The purpose of this letter is to provide advice regarding the Biokit Bioelisa HIV 1 + 2 EIA test kit.

Recommendations

As a result of recent information the Department of Health has taken expert advice which (on the evidence currently available, see background below for details) concluded that:

(a) it is undesirable to use the Biokit Bioelisa HIV 1 + 2 EIA test kit as the sole screening test;

(b) there is no contra-indication for the continued use of this kit, as part of a panel of kits, for confirmatory testing;

(c) there is no justification for retesting stored blood samples or for recalling patients;

(d) the risk to the blood supply is negligible.

Background

The Medical Devices Agency recently received a report in which the Biokit Bioelisa HIV 1 + 2 EIA test kit, when used as a confirmatory test, gave a false negative result with one patient sample. This sample gave unequivocal positive results with a number of other HIV test kits.

As a result of this report, the Department of Health immediately arranged for the Central Public Health Laboratory (CPHL) to assess the performance of the Biokit Bioelisa HIV 1 + 2 EIA test kit against some 500 known HIV positive blood samples. All have registered positive results using this test kit. A further several hundred samples will be examined as soon as possible.

Additional information has become available from the CPHL's ongoing comparative

evaluation programme (funded by the Department of Health) of some commercially available test kits, including the Biokit Bioelisa. One further false negative with the Biokit Bioelisa test kit has now been found in this evaluation..

This test kit has been in use since 1991. The absence of other adverse reports suggests that false negatives involving the use of this test kit are rare.

This letter is being sent to those laboratories which use this test kit, to all blood transfusion services, and to Directors of Public Health for information.

Yours faithfully

ALAN KENT
Chief Executive
Medical Devices Agency

P:\data\press\biokit.emo