NATIONAL BLOOD TRANSFUSION SERVICE

National Director:
H.H. GUNSON, DSc MD FRCP FRCP(Ed) FRC Path.

Deputy Director (Administration):
R.J. MOORE, PhD CEng MIM FIQA

THE NATIONAL DIRECTORATE
GATEWAY HOUSE
PICCADILLY SOUTH
MANCHESTER M60 7LP.

Tel: 061-236 9456

Fax: 061-236 0519

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8th November 1989

Dr. D.A. Kennedy,
Head of Pathology Equipment
and Consumables,
NHS Procurement Directorate,
14 Russell Square,
LONDON. WC1B 5EP

Dear Dr. Kennedy,

PILOT STUDY OF ANTI-HCV DONATIONS

Further to our telephone conversation yesterday, I am writing to give you details of the proposed study which we wish to carry out on behalf of the Department of Health.

The Chiron Corporation have developed a test, called anti-HCV, which has been shown in trials in many countries to detect a marker for non A, non B hepatitis. The test is currently marketed by Ortho Diagnostics Ltd. only, but a licence has been arranged with Abbott Ltd. and they should have tests available by 1990.

In conjunction with the DH, the Transfusion Services in England and Scotland are considering the possibility of introducing this test for routine screening of blood donations. Todate approximately 9000 frozen samples from blood donors have been tested and the seropositivity rate varied from 0.36% to 0.83% in the three RTCs from which the samples were derived. The quality of performance of the anti-HCV test using frozen samples may be in doubt.

Before a decision is made to introduce the test routinely it is important that pilot studies are performed involving the routine prospective use of the test in RTCs. This will not only allow an evaluation of the test on freshly collected blood samples, but also an assessment of how the test can be integrated into working practices.

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The current proposal is to carry out approximately 5000 tests on donations in each of three RTCs, viz. West Midlands, N.E. Thames and Trent and I will co-ordinate the study.

I enclose a draft protocol for the study which I have sent today to the Directors of the three RTCs for their comments. You will note that, for reasons of product liability, it is not proposed to issue products from donation which are repeatably reactive. However, it is not proposed to recall donors for counselling at this time since there are no confirmatory tests available and since some reactions may be false positives, the significance of the result with respect to the health of the donor is not clear. However, it is hoped that estimates of the potential costs involved can be made for future reference.

I wish to thank you for your support in this matter and if you have comments on the protocol I will be grateful if you could fax these to me.

I will send you the final draft of the protocol, hopefully within the next few days.

With kind regards.

Yours sincerely,

GRO-C

H.H. GUNSON,
National Director