NATIONAL BLOOD TRANSFUSION SERVICE

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HHG/LB

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Dr. D. Donald,
Quality Department Manager,
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Dear David,

Thank you for your letter concerning the anti-HIV testing of blood donations. I have to follow up your letter with another question I am afraid in that do you actually submit the protocol for the test as used in each RTC?

There is a debate taking place within the Service at the moment as to whether the definition of a positive result with the combined anti-HIV 1+2 test should be according to manufacturer's instructions or, as strongly recommended by Richard Tedder and Philip Mortimer, should be more severe than the manufacturer's instructions in order that outlying results designated from the bulk of negatives are subject to additional confirmatory testing.

Miss. V.I. Rawlinson, who collates the results of anti-HIV testing on blood donations throughout the RTCs, has recently done a survey of the criteria used for repeating tests in the various Centres. I quote you the report that she has sent to me on this matter.

"The repeat rate with the Wellcome combined kits was 0.84% following manufacturer's criteria, and another 0.14% were repeated for other reasons. While 5 of the 16 Wellcome combined kit users only repeated tests which were positive by the manufacturer's criteria (Bristol, Cardiff, Dundee, Edinburgh and Inverness), 4 had a 10% grey zone (Birmingham, Brentwood, Liverpool and Tooting). One had a 20% grey zone (Belfast), one repeated outliers (Leeds), and one repeated all tests which fell within 3 standard deviations of the negative mean (N. London). The other 4 RTCs who used Wellcome combined kits did not specify any extra criteria, but they only reported repeats in the

manufacturer's positive category. Abbott users only repeated tests which were positive by the manufacturer's criteria. Of the 2 Centres using Behring combined kits, one (Sheffield) repeated 6 which were in a 10% grey zone".

I am trying to establish a uniformed system throughout the Service, but as you can see I still have some work to do.

Yours sincerely,

GRO-C

H.H. GUNSON,
National Director