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VJM/EMT

18 July 1995

Dr Peter Flanagan Clinical Director - Northern Zone Regional Transfusion Centre Bridle Path LEEDS LS15 7TW

Dear Dr

RE:

FEASIBILITY OF THE INCLUSION OF DONORS
WITH AN INDETERMINATE RESULT
IN THE HEPATITIS C LOOK-BACK EXERCISE

Thank you for your letter requesting information about the HCV confirmatory algorithm in use here. For the last four years we have followed the pattern of the Public Health Laboratory at Withington, which has changed with time. The current situation is that a PCR is performed on all samples with EIA activity in two different tests, or, indeed, where one of the two is very strong, (ie x3 controlled value). At the moment RIBA is reserved for results where only one EIA is positive. This confirmatory regime has only been in place for the last 6 months since PCR became a routine.

Initially when HCV antibody screening was introduced in September 1991, referrals were made similarly on the results of 2 screening EIAs, but all single band RIBA reactives reported as indeterminate. The RIBA at that time might therefore have been reported positive with the C100 alone. In order to fulfil the definition set out in your letter, it would be necessary to review all results from 1991 to 1993 to check the initial ones did have a C22.

A couple of years ago, when the third generation RIBA came in, indeterminates were reported on the basis of the presence of C22 and/or C33, and would, therefore, fulfil your criteria if it is assumed that NS3 is equivalent to C33.

As you will see from the information above, there would be no alternative but for us to extract the laboratory results of all indeterminates reported since the 1st of September 1991 to scrutinise them for the appropriate detail. It would take up a lot of time for senior members of staff to embark on this exercise retrospectively. I can therefore assure you that no action will be taken here to extend the Look-Back to this group of donors until there is a direct instruction to do so.

Yours sincerely

GRO-C

Dr V J Martlew

CHIEF EXECUTIVE/MEDICAL DIRECTOR