

MEMORANDUM

To: See Below

From: Dr V J Martlew

Date: 13th May 1991

Ref: VJM/CJW

As you will know it has been recommended by the Department of Health that routine screening of all blood donations for antibodies to hepatitis C is introduced with effect from the 1st September 1991. The delayed implementation date is recommended by the Department since the second generation tests are relatively new and do not yet have F.D.A. Licences. It is therefore necessary for them to undergo validation in the hands of the Service. The Mersey and North Wales Regional Transfusion Service has been asked to participate in a three Centre trial for a minimum period of six weeks to test the Ortho kits of the second generation on all blood donations collected during that period of time. Plasmapheresis donations will not be included during this study.

Any donors found to have a positive result will have the antibody test repeated locally. Repeatable positives will then be referred as a serum sample to the Public Health Laboratory at Withington, Manchester for R.I.B.A. 2 testing and a plasma sample to the Public Health Laboratory at Colindale London for PCR testing. The results of these confirmatory tests will be reported independently back to the Centre and funding will be provided directly to the Public Health Laboratory Service by the Department of Health as arranged by Dr Gunson.

Any donations found locally to have a positive hepatitis C antibody screening test result will be discarded and a note made on the Donor Record for appropriate follow up at the time of their next donation. Since this activity forms part of the validation of a new laboratory test, donor counselling and follow up will not be undertaken as a routine, which antedate routine screening of all donations.

GRO-C

Circulation: Members of the Unit Management Group, Chief M.L.S.O.'s

Copy : Dr H H Gunson

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