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17 May 1991

Dr H L Lloyd MB MRCPATH
Director and General Manager
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Dear Huw,

HEPATITIS C TESTING

Reference:

A. Your XTD^1221/HLL/pk dated 2 May 1991

Thank you for your letter which was awaiting my return from overseas. I must apologise for not replying sooner, the cause was not idleness, just absence, but with leave.

To answer your specific question, we do not test any donations at the ABSD for Hepatitis B core or measure the ALT levels. The only tests that we perform in addition to normal screening are, CMV testing on selected donations for transfusion to neonates and immunocompromised patients, and ALT levels on plasma drawn by apheresis which is destined for intravenous immunoglobulin production.

I must say that I was personally dismayed to learn that you are going to break ranks over the agreed policy on the introduction of Hepatitis C testing. As someone who might be considered an outsider and therefore not bound by the collective decision, I believe, and this is the policy of my Director General, that it is vital that we maintain a common front. Only in this manner are we going to navigate the difficult waters ahead engendered by the introduction of product liability and our requirement to be licenced by the Medicines Control Agency.

HHG 5/44

The second generation HCV tests have not yet been validated in this country and we do not know, as yet, whether the recombinant antigen used in the test, and derived from a US strain of the virus, will be equally effective in UK. It also appears that the only validation has been performed by the manufacturers. I believe that we would be laying ourselves open to criticism and possible legal action if we use a test which has not been fully trialled in this country. I will certainly be advising the Surgeon General that we should move in consort with the rest of the NBTS.

With best wishes

Yours sincerely

GRO-C