



THE LEICESTER ROYAL INFIRMARY

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Department of Haematology

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Our Ref: VEM/jg

3rd April 1987

Mrs L Frith
Sales Development Manager
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Rec'd. 9/4/87.

Dear Linda

You will probably have heard about the conversation I had with Ann about the seroconversion of one of our patients to Hepatitis B antigen positivity. The patient in question, Mr GRO-A is registered at another Haemophilia Centre but was referred to Leicester for cardiac surgery. His previous treatment consists of cryoprecipitate and commercial concentrate in 1982 and cryoprecipitate in 1984. His cardiac catheterization had been covered with DDAVP. He was first seen for assessment in this Haemophilia Centre in June 1986 when he was found to be Hepatitis B antigen negative, Hepatitis B antibody negative. Once we had demonstrated that he was neither infected nor immune we applied to our local consultant virologist for a supply of Hepatitis B vaccine. This is the procedure we have to follow. This was issued and he was given his first dose of Hep B vaccine on 14th August and a second dose on 19th September. The cardiothoracic surgeons tested him for Hepatitis B antigen on 25th September and again when he was admitted on 7th October. Both of these were negative. He underwent open heart surgery on 8th October when he had triple coronary artery by-pass grafts. During the course of the operation he had 2 units of whole blood and 6 units of platelet concentrate issued by the Blood Transfusion Service. Pre-operatively and for 10 days post-operatively he was treated with Cutter Koate HT Factor VIII concentrate, receiving a total of 51 bottles of batch 50R004. On 19th February he was given his third injection of Hepatitis B vaccine and attended the centre on 19th March for Hepatitis B antibody testing which is routinely done 1 month after the third dose of vaccine has been given. To our great surprise and considerable concern this sample proved to be Hepatitis B antigen positive. We retrospectively tested a sample from 19th February which had been taken for HIV antibody testing. This sample also proved to be Hepatitis B antigen positive. I hope this letter contains the information required, if not then please do not hesitate to get in touch with me.

Yours sincerely

GRO-C

Dr V E Mitchell,
Consultant Haematologist

C O M P L A I N T S L O G

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DIVISION - CUTTER

COMPLAINT NO: 1

csr 30327

DATE OF RECEIPT OF COMPLAINT	PRODUCT	PARTICULARS OF COMPLAINANT	NATURE OF COMPLAINT	ACTION TAKEN	DATE CUTTER USA NOTIFIED	ACTION TAKEN BY CUTTER USA
3 April 87	KOATE HT	Name: Dr V Mitchell Address: Leicester Royal Infirmary Tel no: (0533) 541414 ext: GRO-C	Patient positive for HB _s Ag	Further info obtained from Dr Mitchell rec'd 28.4.87 Meeting held 28.4.87	Cutter notified by fax 28.4.87 Medical Incident Report filed with Cutter 29.4.87	Letter from Dr Akin sent direct to Dr Mitchell May 14 1987