



**Response to Questions Raised at the Inquiry
into
Contaminated Blood and Blood Plasma Products**

**2. Testing Coagulation Factor Concentrates for
Evidence of Contamination with HIV**

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Testing Coagulation Factor Concentrates for HIV-Contamination

In their evidence to the Inquiry, in a section headed “*Delays in Heat Treatment, Testing and Screening*” (first submission from the Haemophilia Society, p. 24) the Haemophilia Society claimed that “*By the summer of 1983, a rudimentary test was developed that could have been used to test each batch of blood products.*”

The screening test referred to by the Haemophilia Society functioned by detecting antibodies to HIV and is known as the ELISA (enzyme-linked immunosorbent assay) test. ELISA kits for testing blood plasma samples for antibodies to HIV became available commercially during 1985.¹

SNBTS used the HIV-ELISA to screen batches of Factor VIII concentrate routinely when the test became commercially available, although the test had been designed and licensed for testing samples of blood plasma or serum, not plasma products. Earlier batches of SNBTS Factor VIII concentrate were also tested using the HIV-ELISA, including batches implicated in the transmission of HIV. No positive batches were ever detected (SNBTS unpublished results).

In the USA, dozens of batches of Factor VIII concentrate were studied for evidence of contamination with HIV but all results were negative.^{2,3}

It was not until 1991 that it became technically possible to identify batches of Factor VIII concentrate contaminated with HIV. This was achieved using a new analytical technique (known then as polymerase chain reaction, PCR, but now referred to as nucleic acid amplification technology, NAT) which was much more sensitive than the ELISA method and which could detect HIV directly.⁴⁻⁶

The date of summer 1983, given by the Haemophilia Society, refers to the date on which the very first research experiments were performed using an ELISA method to try to detect antibodies to LAV, a putative AIDS virus. This research was begun at the Institute Pasteur in Paris in July 1983,⁷ and the results and details of the ELISA method developed at the Institute Pasteur were published in June 1984.⁸ It was in May 1984 that HIV-antibodies were confirmed as being associated with the virus responsible for AIDS by a similar ELISA method which had been developed at the USA National Cancer Institute (NCI).⁹ Prior to these publications, patent applications for an HIV-ELISA test had been filed by both the

Institute Pasteur and by the NCI. A USA patent was granted to the NCI in May 1985.¹⁰ Subsequently, in September 1987, the Institute Pasteur and the NCI were assigned joint inventorship by the US patent office.¹¹

The ELISA test required specialised reagents and commercial manufacture was necessary to provide users with suitable materials for performing the test. Prior to the USA patent being granted to NCI, licences for manufacture of the test had been awarded to several companies in the USA¹² but, as the test was classified as a medical device, applications from each of the companies had to be approved by the Food and Drug Administration (FDA) before their test could be made commercially available. Test kits manufactured in the USA cannot be exported without an FDA licence, so commercial kits from the USA were not available in the UK prior to FDA approval and manufacture of the NCI HIV-ELISA was restricted by the US government to USA companies that had already been awarded commercial licenses. FDA approval was first given to a licensee of the NCI test in March 1985, but difficulties in scaling-up manufacture meant that supplies were limited until late-1985.¹³ The company licensed by the Institute Pasteur had its HIV-ELISA test approved by the FDA in February 1986.¹⁴

In summary, the claim by the Haemophilia Society not only concerns a test that was unable to identify batches of HIV-contaminated coagulation factor concentrates, but also the claim that testing could have been conducted from the date:

- on which the first research experiments using an ELISA test were conducted.
- which preceded publication of the findings of these researchers by 11 months.
- which preceded the availability of a commercial HIV-ELISA test by at least 20 months.

In addition, the date given by the Haemophilia Society precedes by eight years the development of an analytical technology that was able to identify batches of coagulation factors that were contaminated with HIV.

References

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