

NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL Holly Hill, Hampstead, London, NW3 6RB

NATIONAL BIOLOGICAL STANDARDS BOARD

A W.H.O. International Laboratory for Biological Standards

DPT/MGS/82/737

telegrams Nibsac London NW3 telex 21911 (Nibsac Ldn) telephone 01-435 2232

17th March 1982

Mr. T.J. Snape,
Blood Products Laboratory,
Dagger Lane,
Elstree,
Borehamwood,
Herts.

Dear Terry,

Testing of Factor VIII, Factor IX, albumin and plasma protein fraction

The question you raise about the extent of NIBSC testing of these NHS-produced products is not one to which I can give you an immediate answer. I will need to raise the issue with the DHSS and also with our Scientific Policy Advisory Committee. My own view is that testing one batch of each product every month is about right, although it may be possible to reduce the frequency somewhat. You will be aware that we test samples from every batch of the comparable commercial products, although I recognize that their batch sizes are usually much larger, and it was because of this that we restricted the amount of testing that we carry out on NHS-produced material.

As far as discussing the results of our testing is concerned, you can rest assured that we would let you know immediately in the event of any serious disagreement between our findings and yours. As you know, it has not been the practice of NIBSC to discuss with manufacturers the results of testing carried out on their products. However, I would be very willing to have informal discussions with you about the results of our tests on your products, although I suggest we postpone such a meeting until Trevor Barrowcliffe returns in July.

Yours sincerely,

GRO-C

Duncan P. Thomas

Head, Division of Blood Products