MRG

Medical Research Council

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Standards and Control

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11th June, 1975

GRO-C: John Watt FILE

VACTOR VIII

Dr. J.P. Cash, Regional Blood Transfusion Service, Royal Infirmary, EDINBURGH, EH3 9HB

Proposed 5th British Plasma Standard for Factor VIII

Dear Dr. Cash,

This preparation, which is intended to replace the 4th British Standard for factor VIII, will shortly be available, and we would like to ask for your help in its calibration. As on previous occasions, this will be a collaborative study with several laboratories each carrying out assays by their own methods.

The main aim of the study will be to estimate the potency of the proposed standard by comparison with the first International Standard for factor VIII. We would remind you that the International Standard gives a positive result for hepatitis B antigen; the proposed 5th British plasma standard is H B Ag negative.

The enclosed description gives details of the study, and if you would like to take part, we would be grateful if you could fill in the questionnaire. You will then be sent a detailed design of the assays for your laboratory, together with the coded samples.

Yours sincerely,

**GRO-C** 

-C

T.W. Barrowcliffe Scientist GRO-C

T.B.L. Kirkwood Statistician

Encl.

#### CALIBRATION OF 5TH BRITISH STANDARD FOR FACTOR VIII

#### Aims

The aims of the calibration is to measure the potency of the proposed 5th British Standard (plasma) against the 1st International Standard (concentrate). The results will also be analysed to check whether initial dilution of the concentrate in haemophilic plasma or buffer produces significant differences in potency levels and precision. Samples of the 4th British Standard will be included in some laboratories to check its loss of potency.

# Materials and Coding

All ampoules will be coded, but because of the distinctive nature of the International Standard, it would be helpful if a responsible person in each laboratory could make up the initial dilutions and transfer these to coded tubes.

## Design and Number of Assays

Each laboratory will be asked to do 12 assays. If more than one operator is assaying simultaneously, only one ampoule of each material need be opened, so that two operators would perform assays of six ampoules, and 3 operators would each do 4 ampoules of each material.

# Other Clotting Factors

This plasma standard for factor VIII could also serve as a useful reference material for other clotting factors. For factor IX an International Standard is now available and the plasma could be calibrated against this, but for the other factors assays would have to be against pooled plasma. If your laboratory is willing to do some of these extra assays, it would be helpful if you could fill in the details on the questionnaire.

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