

SUPERNINE PROJECT

1970 PROJECT COMMENCED

PARTICIPANTS:

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AIM

TO REPLACE DEFIX WITH A CONCENTRATE 3-5 TIMES MORE POTENT
AND WITH REDUCED HBsAg CONTENT.

APPROACH

USE PEG 4000 TO REMOVE HBsAg FROM DEFIX AT pH REMOTE FROM
THAT OF FIX IEP, THEN PRECIPITATE FIX AT ISOELECTRIC
POINT. OPTIMISE RECOVERY OF FIX AND REMOVAL OF HBsAg BY
MANIPULATION OF pH, PROTEIN CONCENTRATION, IONIC STRENGTH,
PEG CONCENTRATION.

1973 MARK I PRODUCT USED IN CLINICAL TRIALS

MARK II DEVELOPMENT INITIATED

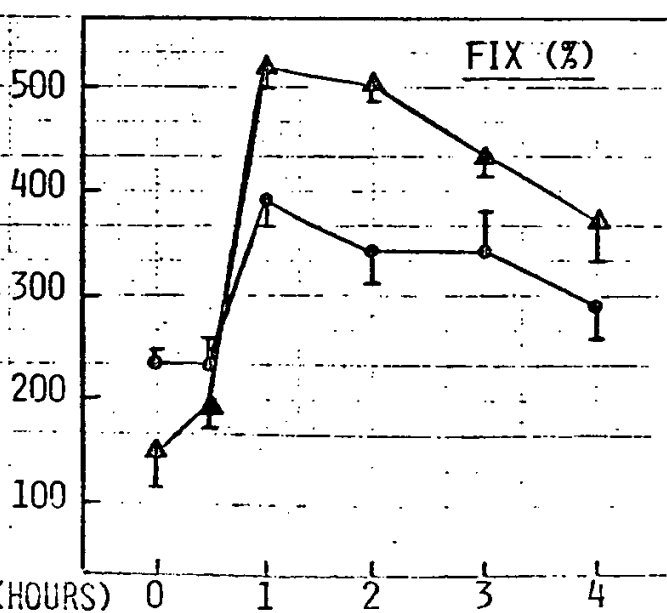
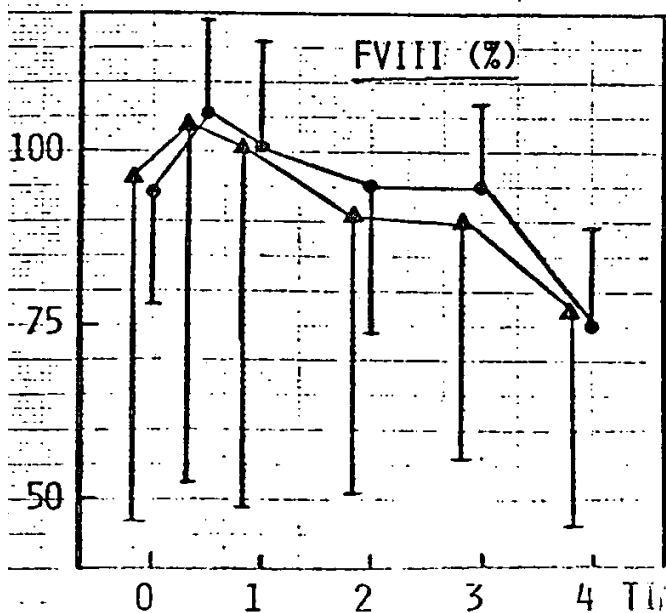
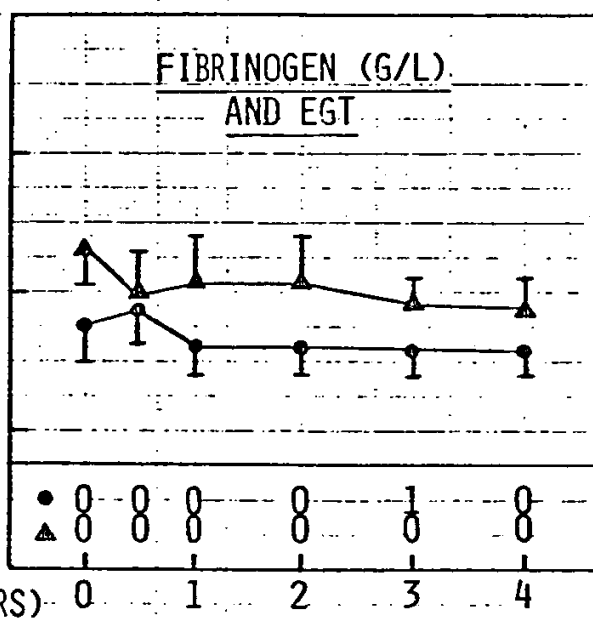
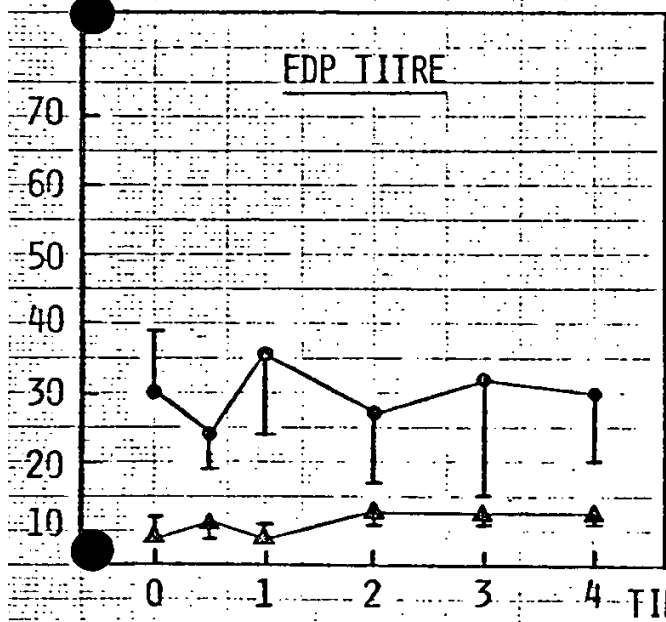
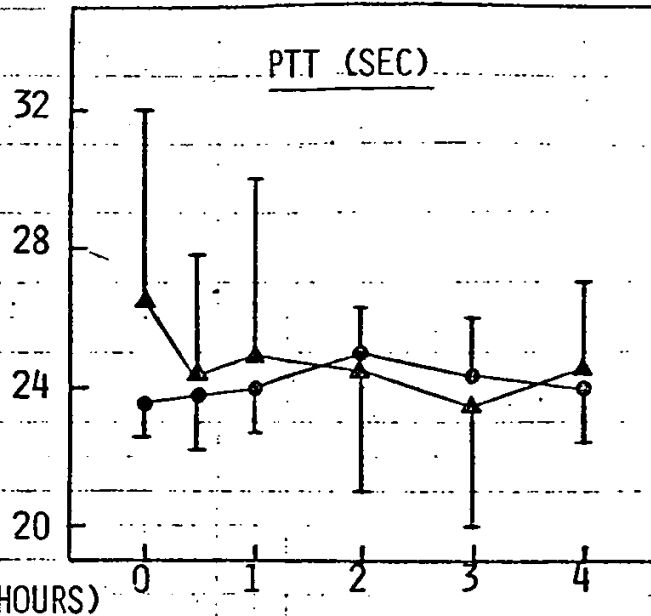
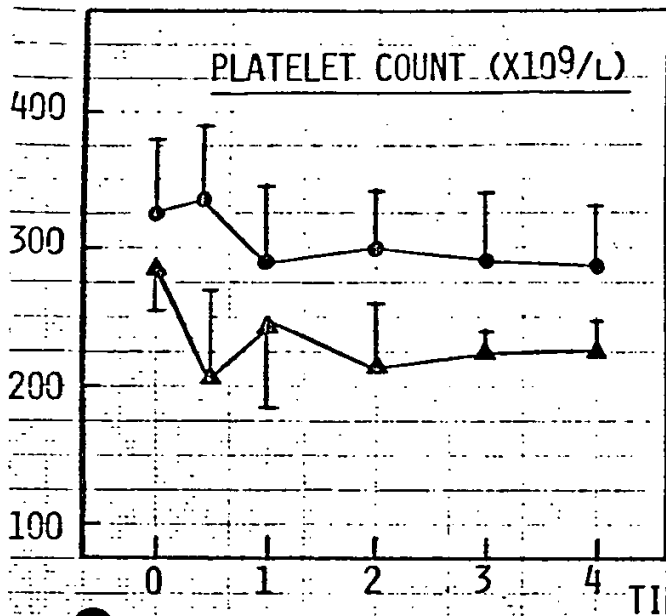
1976 MARK II CHEMISTRY FINALISED

SCALED-UP PRODUCTION INITIATED

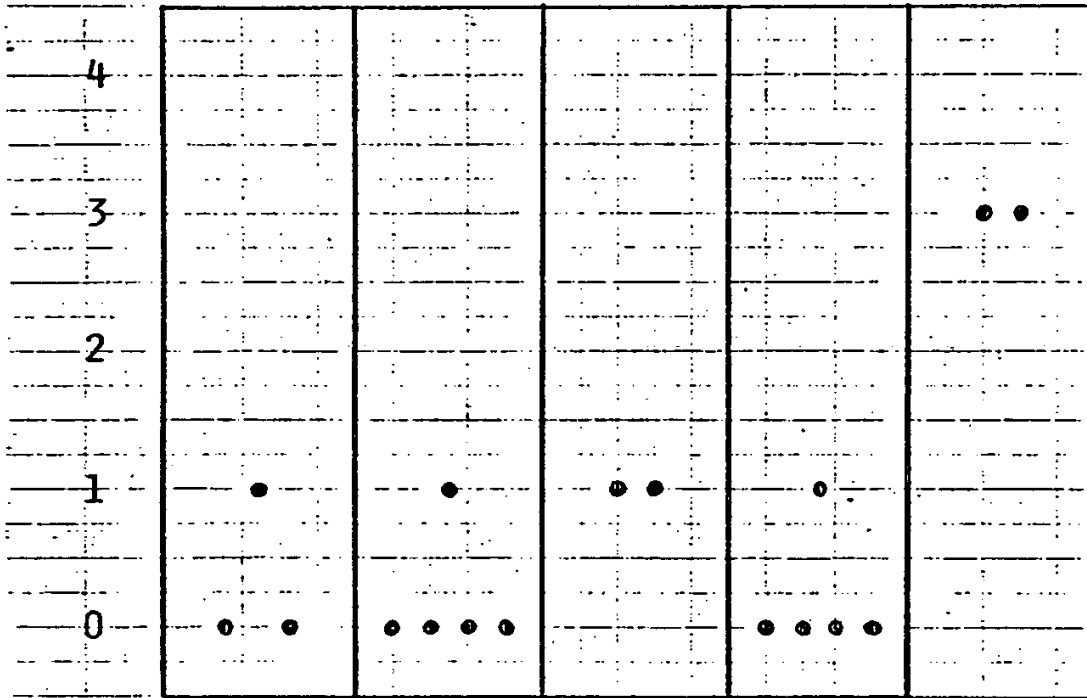
1977 ROUTINE PRODUCTION - USING FAILED DEFIX LOTS

NON-STASIS MODEL
(PROWSE)

- DEFIX AT 100 U FIX/KG (N = 5)
- ▲ SIX, 100 AT 200 U FIX/KG (N = 2)



WESSLER TEST (PROUSE)



PRODUCT: — SIX — DEFIX — DEFIX — OXFORD — OXFORD
 BATCH : 100 192 192 9D834 9D834
 DOSE (u/kg): 50 30 45 30 45

ADVANTAGES OF SUPERNINE

1. INCREASED POTENCY OF FACTORS II, IX & X
2. REDUCED INFUSION VOLUME
3. REDUCED RISK OF SIDE EFFECTS/ADVERSE REACTIONS
 - 3.1 HEPATITIS
 - 3.2 THROMBOGENICITY
 - 3.3 ALLERGIC REACTIONS
 - 3.4 NO FVIII:CAG