NZBS Use Only:

FRACTIONATED BLOOD PRODUCT - ADVERSE EVENT NOTIFICATION

Recipient Details (pre-printed label may be used)				
Family Name	First Names	National Health Index No.	Weight (kg)	Height (cm)
Address		Date of Birth (dd/mm/yyyy)	Gender ☐Male ☐Female	Pregnant ☐Yes ☐No or N/A

Diagnosis and Indication for Fractionated Blood Product (include relevant medical history/allergies/surgery/LMP if pregnant):

Suspected or Implicated Fractionated Blood Product(s) - *add a separate page if necessary*

Blood Product(s)	Dose / Volume Prescribed	Route	Date Given	Start time	Dose/Volume Administered	Stop time (infusions only)	Batch Number(s)

***If an IV or SC product*:** Infusion Rate - *at start*: _____ *mL/hr* Infusion Rate - *at time of reaction*: _____ *mL/hr*

***If a freeze dried product*:** The solvent used to reconstitute: ☐ As supplied ☐ Other: (specify)

Description of Adverse Reaction or Event (signs, symptoms, relevant test results) **–** *add separate page if necessary*

Date adverse event detected: / / 20

Details:

Treatment of Adverse Reaction or Event (include any medicines given, with dose/route)

Other Medicines in Use (include any premedications, anaesthetic agents and 'over the counter' products) – *add a separate page if necessary*

Medicine	Daily Dose (with units)	Route	Date Started *or* >3 months	Date Stopped *or* Ongoing	Indication(s) for Use

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Assessment and Imputability of Adverse Event

Previous therapy with suspected blood product? *(summary only)* ☐ Yes ☐ No ☐ Not applicable

- *Product Name:*
- *Date Started:*
- *Frequency:*

Has the suspected blood product been tolerated in the past? ☐ Yes ☐ No ☐ Not applicable

After stopping suspected blood product, did the reaction abate? ☐ Yes ☐ No ☐ Not applicable

If the blood product was re-introduced, did the reaction reoccur? ☐ Yes ☐ No ☐ Not applicable

Was the event classified as serious? *(Was treatment needed to preserve life?)*

☐ **Yes** ☐ **No**

If yes, *please tick at least one of the following outcome boxes:*

☐ Life-threatening
☐ Persistence of significant disability / incapacity
☐ Required intervention to prevent permanent impairment / damage
☐ Congenital anomaly / birth defect
☐ Required hospitalisation or hospitalisation was prolonged
☐ Suspected infusion of an infectious agent

If no, *did the patient require hospitalisation or was hospitalisation prolonged?* ☐ Yes ☐ No ☐ N/A

Causality Assessment:

Likely correlation to blood product

☐ Highly probable
☐ Possible
☐ Unlikely
☐ Unassessable
☐ Unrelated

Case Outcome: *(on the day of reporting this event)*

☐ Recovered: Date _____ Time _____ *or* ☐ Not yet recovered
☐ Recovered with sequelae (specify):
☐ Permanently disabled
☐ Death: Date _____ Autopsy: Date _____ *or* ☐ not undertaken

Report type: *(please tick all that apply)*

☐ Product used for a MedSafe-registered indication	☐ Section 29 Medicine	☐ Medication error
☐ Incorrect product transfused	☐ Overdose	☐ Under-dose
☐ Pregnancy	☐ Lactation occurring	☐ Quality defect in product
☐ Lack of effect	☐ Idiosyncratic effect	☐ Unexpected therapeutic benefit
☐ Occupational exposure	☐ Off-label use	☐ Misuse

Adverse Event Reported by: (essential)	**Treating Specialist/GP/Midwife: (essential)**
Name/Role: Organisation and Address: Phone: EMAIL: (essential) **DATE:**	Name/Role: Organisation and Address: Phone: EMAIL: (essential)
If the reporter is the patient, has consent been given by the patient to contact the treating specialist to follow-up the adverse event ☐ Yes ☐ No	**Registrar name and email:** *(if relevant)*

Return the completed form to the Blood Bank as soon as possible.
If the adverse event is serious, please contact a Transfusion Medicine Specialist, via your local Blood Bank.

Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax
Auckland	09 307 2834	09 307 2823	Palmerston North	06 350 8558	06 357 2854	Christchurch	03 364 0310	03 364 0159
Waikato	07 839 8919	07 858 0988	Wellington	04 918 6961	04 385 5982	Dunedin	03 470 9369	03 470 9513

The Blood Bank on receipt will forward this form to the NZBS National Reporting Centre via:

Adverse.Reaction@nzblood.co.nz (preferred) **or Fax (03) 470-9513** (if no facility to email)

The NZBS National Reporting Centre will notify the manufacturer, and if indicated, MedSafe and CARM.