

**NRL**

National Serology Reference Laboratory, Australia
4th Floor, Healy Building, 41 Victoria Parade, Fitzroy, Victoria, 3065
Telephone: +61 3 9418 1111 Facsimile: +61 3 9418 1155

The Secretary
Review of Australia's Plasma Fractionation Arrangements
Department of Health and Ageing
GPO Box 9894
Canberra ACT 2601

Dear Sirs,

The National Serology Reference Laboratory, Australia (NRL™) delivers an unparalleled, multifaceted national and international programme to assure quality in laboratory tests for highly transmissible agents such as Human Immunodeficiency Virus (HIV and hepatitis. We provide a high level of assurance for sero-diagnostic test kits and testing protocols, for blood services, plasma fractionation services and diagnostic and therapeutic testing programmes and perform scientific research in areas related to HIV. NRL is the international leader in quality assurance of testing for HIV and other blood-borne viruses.

The delivery of quality programmes to national and international groups and services that assure the safety of transfusion products puts NRL in a position to comment on maintaining safety of the Australian products.

The NRL does not wish to comment on aspects of Plasma Fractionation Arrangements which are beyond its scope of practice. We make the following points:-

- In Australia the evaluation-registration system of test kits for transmissible infections is as safe as any but probably provides a higher degree of safety to blood testing than anywhere else. The NRL evaluates test kits registered elsewhere in the world that do not meet Australia's registration standards. In the USA for example, blood is screened using kits that were discarded from use in Australia in the mid-1990s.
- Testing in the Australian Red Cross Blood Service laboratories, where the evaluated and registered kits are used, is monitored on a day-to-day basis. There are controls for observing inadequately performing batches of test kits, changes in the performance of an instrument or identifying a technician who needs further training. This is not monitored independently in blood collection services elsewhere in the world.
- All ARCBS laboratories are licensed to the code of GMP which is maintained at a standard not observed in many parts of the world.
- The supply of blood and blood products in Australia may not be sufficient to meet demands in the future but with relatively small adjustments to the donor base the supply and self sufficiency could be maintained. The Committee's attention is drawn to the splendid PhD Thesis of Professor Gordon Whyte's on this matter.
- The use of kits below standards observed in Australia to screen blood and plasma will not obey the principle of zero risk held in Australia.

The NRL will continue to underpin the safety, quality and efficacy of testing of blood products to assure Australian users of plasma products the best quality products.

Yours faithfully,

**Elizabeth M. Dax, AM, MD, BS; PhD, APACP
DIRECTOR**

St Vincent's Institute of Medical Research under the care of St Vincent's Health
The NRL is a WHO Collaborating Centre
A.C.N. 004 705 640

