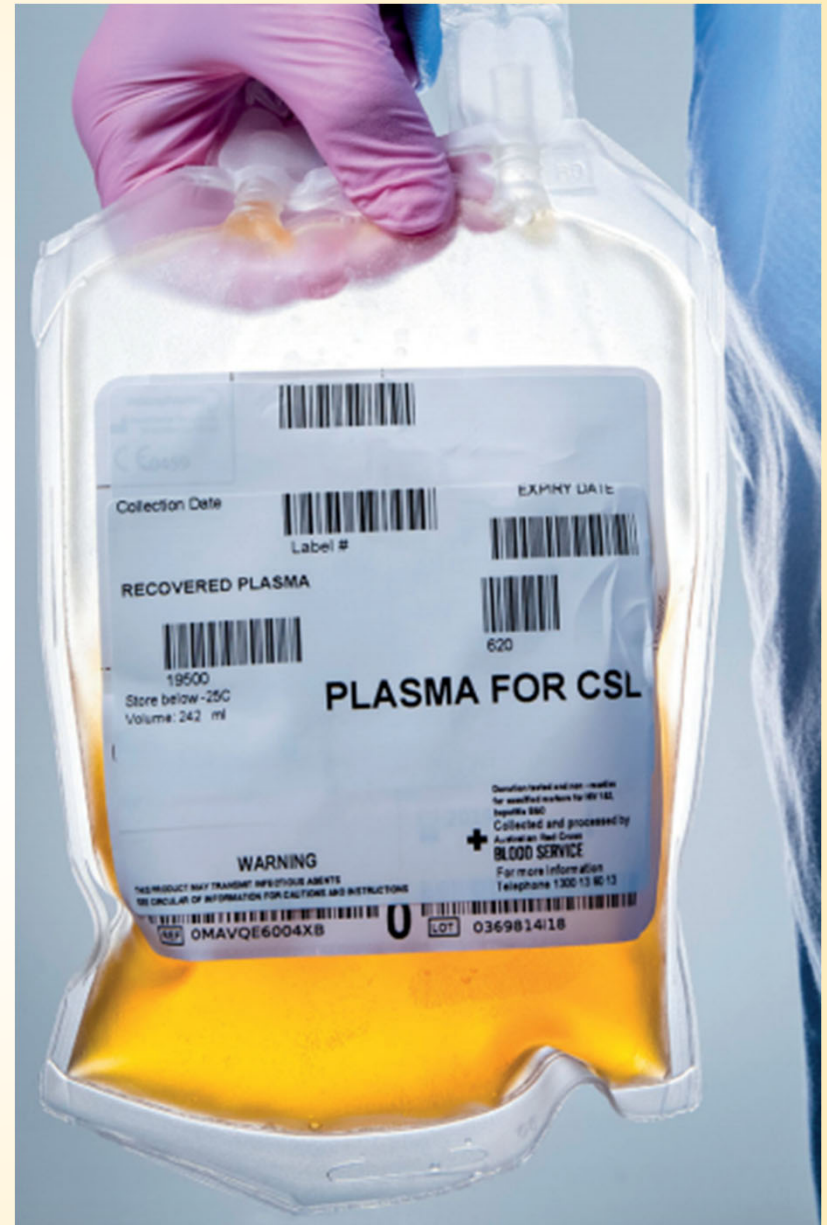


# Liquid Gold

## The Australian Plasma Industry



# Quick facts

- ▶ Constitutes 55% of whole blood and is 90% water
- ▶ Carries cells, nutrients, salts, minerals, enzymes around the body
- ▶ Aids removal of waste from cells and body
- ▶ Contains immunoglobulins, proteins and clotting factors



# Quick facts

- ▶ AB blood group is the universal donor group
- ▶ 1 in 3 require blood or blood products in their lifetime
- ▶ 3% will donate each year
- ▶ You are eligible to donate between 18 and 70 years
- ▶ In 2016, only 64% of the population were of eligible age to donate



# Australian Red Cross Blood Service (ARCBS)

- ▶ Collections per day
  - ▶ Whole blood – 3,800
  - ▶ Plasma – 1,300
- ▶ 97,635 new blood and plasma donors in 2016-2017
- ▶ Plasma products
  - ▶ Fresh Frozen Plasma (FFP)
  - ▶ Cryoprecipitate
  - ▶ Cryo-Depleted Plasma (CDP)



# History of Issues with Plasma Donations and Transfusions

- ▶ In 1983, there was the first evidence which connected alloantibodies (HLA and HNA) with TRALI
- ▶ Transfusion-Related Acute Lung Injury (TRALI)
- ▶ Life-threatening complication characterised by acute development (within 6 hours) of respiratory distress and signs of pulmonary oedema with no underlying cause
- ▶ It has been associated with almost all blood components
- ▶ The majority of cases were associated with plasma-containing components from female donors with leukocyte antibodies
- ▶ These antibodies are generally present in women who have been previously pregnant



# Mitigation strategies

- ▶ All over the world strategies have been implemented to reduce TRALI from plasma products
  - ▶ In 2007 ARCBS began transitioning to plasma products only from male donors
  - ▶ Completed in July 2012 and remains male-only today

Can females still donate plasma?

- ▶ Yes, the plasma donated from females joins part of the majority of plasma which is sent for fractionation
- ▶ Can be used without issues of TRALI



# CSL Behring

- Started in 1916
- National Fractionator since 1952 and one of the largest biopharmaceuticals in the world
- R&D developing break-through medicines for
  - Plasma Therapies
  - Recombinant Proteins
  - Gene Therapy
- Produces 18 life saving products from donated plasma



# Factors and Concentrates

## Prothrombin complex concentrate (PROTHOMBINEX®-VF)

Helps stop severe bleeding – due to warfarin (a blood-thinning medication) for example.

**500 IU vial = 9.5 blood donations  
or 4.2 plasma donations**

## Factor IX concentrate (MonoFIX®-VF)

Used to treat people with the inherited bleeding condition haemophilia B.

**500 IU vial = 31.1 blood donations  
or 13.9 plasma donations**

## Factor VIII and VWF concentrate (BIOSTATE®)

Treats patients with haemophilia A and von Willebrand disease.

**500 IU vial = 13.7 blood donations  
or 6.1 plasma donations**

## Antithrombin concentrate (THROMBOTROL®-VF)

Helps prevent blood clots in patients with an inherited deficiency of antithrombin. Most commonly used at times of surgery and childbirth.

**1000 IU vial = 20.1 blood donations  
or 9.0 plasma donations**

## Albumin (ALBUMEX® 4)

For treatment of patients suffering from shock due to blood loss, during heart-lung bypass surgery and plasma exchange.

**500 mL vial = 2.7 blood donations  
or 1.2 plasma donations**

## Albumin (ALBUMEX® 20)

A stronger concentration of Albumin used when the levels of albumin in blood is low.

**100 mL vial = 2.8 blood donations  
or 1.2 plasma donations**



# Immunoglobulins

## Intravenous Immunoglobulin IVIg (INTRAGAM® P)

Used to replace antibodies to help prevent infections and also used in the treatment of some immune, blood and neurological disorders.

Made in two vial sizes.

**200 mL vial = 7.8 blood donations  
or 3.5 plasma donations**

## Rh(D) Immunoglobulin-VF

Also known as anti-D. Used to prevent haemolytic disease of the newborn in babies, which can result in serious health problems for the baby or even a miscarriage. 17% of Australian mothers will need injections of anti-D.

**625 IU vial = 0.1 blood donations  
or 0.04 plasma donations**

## Intramuscular Immunoglobulin (Normal Immunoglobulin-VF)

Used for passive immunisation against hepatitis A, measles and poliomyelitis.

**5 mL vial = 0.7 blood donations  
or 0.3 plasma donations**

## Tetanus Immunoglobulin-VF (for IM use)

Used for passive immunisation against tetanus.

**250 IU vial = 0.3 blood donations  
or 0.1 plasma donations**

## Tetanus Immunoglobulin-VF (for IV use)

Used in treating tetanus.

**4000 IU vial = 4.2 blood donations  
or 1.9 plasma donations**

## Zoster Immunoglobulin-VF

Is used for the prevention of chicken pox and shingles in people with weakened immune systems, such as patients with leukaemia, lymphoma, and immunodeficiency.

**200 IU vial = 0.3 blood donations  
or 0.1 plasma donations**

## Hepatitis B Immunoglobulin-VF

For passive immunisation against hepatitis B.

**400 IU vial = 0.04 blood donations  
or 0.16 plasma donations**

# Plasma Industry

- ▶ 2016/17 – 637 tonnes of Australian Plasma was pooled for fractionation with an estimated 42-45 million litres worldwide
  - ▶ Increasing ~10% per year
- ▶ IgG is the current major plasma protein in terms of clinical applications and therapeutic importance
  - ▶ 11.2% increase in 2016/17 financial year
- ▶ 56% was domestically produced, with 44% imported

## Costs

- ▶ 2016-2017 – \$504.6 million
  - ▶ Increased by \$0.5 million from the previous financial year

## **BLOOD FACT**

IVIg is very precious and is currently worth more than twice the price of gold on a gram-for-gram basis. For the patients who need it though, it's priceless!

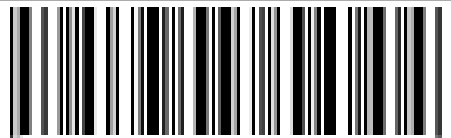




# Maximising Products and Reducing Waste

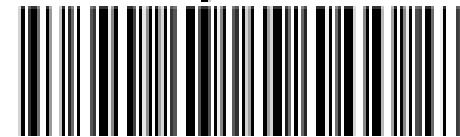
- ▶ In 2013, a cost indicator was included on all blood bags
- ▶ Aimed at minimising unnecessary wastage of a valuable resource
- ▶ Increase awareness on associated costs even though there is no cost to the patient
- ▶ Donations are voluntary but testing, processing and distribution have costs
- ▶ Last year our lab had a wastage of approximately 92 units of plasma products (FFP, Cryo, CDP) that were ordered (thawed) and not used . This accounts for 17.8% of total wastage and approximately \$16,238

Collection Date  
16 Apr 2013



Label # 1604011

EXPIRY DATE  
28 May 2013 23:59



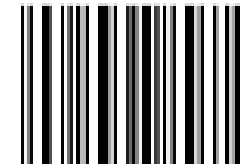
**RED CELLS in SAG-M**  
Leucocyte Depleted



04390

Store at +2C to +6C  
Volume: 246 ml

**A**



060

**Rh D NEGATIVE**

Manufacturing cost \$345.45

## TRANSFUSION INSTRUCTIONS

- 1 PROPERLY IDENTIFY INTENDED RECIENT
- 2 DO NOT USE IF CONTENTS SHOW VISIBLE SIGNS OF DETERIORATION

## WARNING

THIS PRODUCT MAY TRANSMIT INFECTIOUS AGENTS  
SEE CIRCULAR OF INFORMATION FOR CAUTIONS AND INSTRUCTIONS

Donation tested and non - reactive  
for specified markers for HIV 1&2,  
hepatitis B&C, HTLV and syphilis.

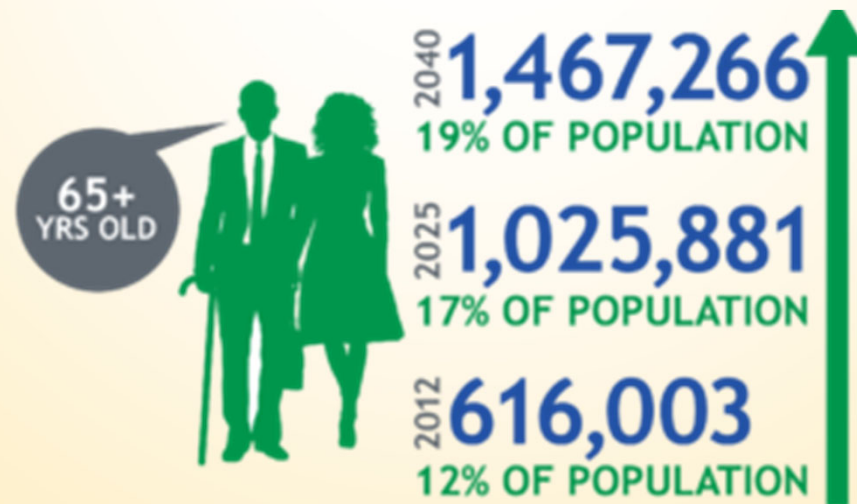
Collected and processed by  
**Australian Red Cross**  
**Blood Service**

For more information  
Telephone 1300 13 60 13



# Future?

- Each week, Australia needs more than 25,000 donations (overall) to keep up with demand for blood and blood products and that demand is expected to grow by 100% over the next 10 years
- The aging population is expected to be a major driver for increased demand for blood and blood products, while also impacting on the available donor pool



Source: Colorado State Demographers Office, 2013

# Future?

- Currently IgG is the main driver for plasma fractionation and it is unrealistic to imagine an IgG recombinant product with the same versatility as the plasma counterpart over the next few years
- To combat this, the criteria for clinical use of Ig in Australia is undergoing its third update and planned release on October 22, 2018 in BloodSTAR
  - Some patients may no longer be approved for continued IVIg use



# What can we do?

- ▶ The blood service has recently opened two plasma only donor centre in Townsville and Canberra as a trial to try combat the rising demand for plasma
- ▶ First time donors will be able to donate plasma as compared to a whole blood donation
- ▶ Estimated to produce an additional 17.5 tonnes of plasma per year





Roll Up Your Sleeves!

**THE POWER  
IS IN YOUR  
PLASMA**



**[donateblood.com.au](http://donateblood.com.au) or Call 13 14 95**

Thank you!

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