

Registration

Health

Exam

Testing

2

3

## Procedure

Present a valid photo ID, proof of address and SIN card

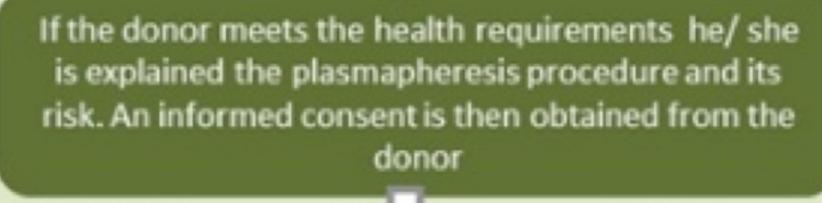


EVERY donor must complete a comprehensive questionnaire detailing donor's past and current medical history and lifestyle

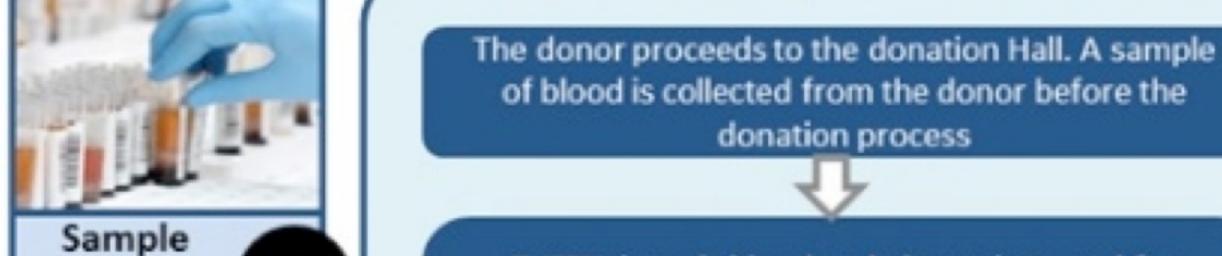
Meet Health Canada's requirements for:

- Age (≥17 and <68 years of age) and weight</li>
- II. Blood Pressure
- III. Pulse
- IV. Hemoglobin levels
- V. Body Temperature

Donor proceeds to the private screening rooms



Physician or Physician Substitute (R.N) reviews donor's completed questionnaire, overall health and performs a physical exam



EVERY donor's blood and plasma is tested for transmissible disease markers as required by Health Canada and FDA. These include: HIV-1 and 2, Hepatitis B and C, Syphilis. Hepatitis A and Parvo B19 are also tested as per IQPP requirements

A sample of plasma is collected from the donated plasma bottle after donation

Donor cannot proceed if he/she fails to meet any criteria at this stage

Selective Removal

Donor cannot

proceed if

he/she fails

to meet any

criteria at

this stage

Donor cannot

proceed if

he/she fails

to meet any

criteria at

this stage



Only units that are free of transmissible disease markers, correct physical characteristics such as color, turbidity and volume are released

EVERY unit must test negative for HIV, Hepatitis A, Hepatitis B, Hepatitis C, Syphilis and Parvo B19 before it is deemed acceptable for release. For units donated by applicant donors\* the acceptable test results must be indicated on two separate donations. The units are held in quarantine until then. In case of positive test results a look-back procedure\*\* is initiated



All donated plasma units are maintained at controlled temperatures (≤ -20 ° C) to prevent loss of life saving plasma proteins. Validated freezers with temperature monitoring are used for plasma storage

All donated plasma units are maintained at controlled temperatures (≤ -20 ° C) during shipping for the same reasons



The purified final protein products further undergo nanofiltration ( using nano membranes), sterile filtration and/ or terminal dry-heat treatments for plasma protein product quality and recipient safety

Once shipped to the fractionator all plasma units are pooled and undergo validated viral and prion inactivation steps such as combination of solvent and detergent incubations, pasteurization (60 \* C for 10h), low pH or acid treatments.

All plasma

units failing to

meet the

temperature

requirements

are discarded

Reactive units

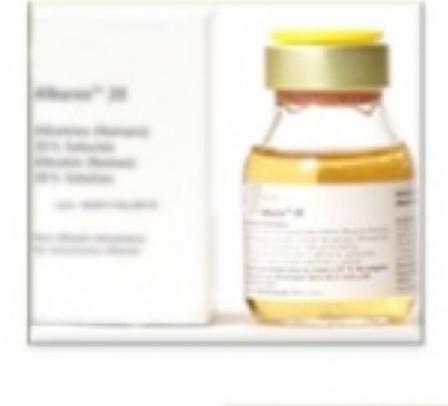
are discarded

as defined by

the Canadian

Regulations

Plasma products that fail to meet stringent quality requirements are discarded



After many layers of screening, testing and quality checks source plasma is used for manufacturing of safe and compliant plasma protein therapies.

