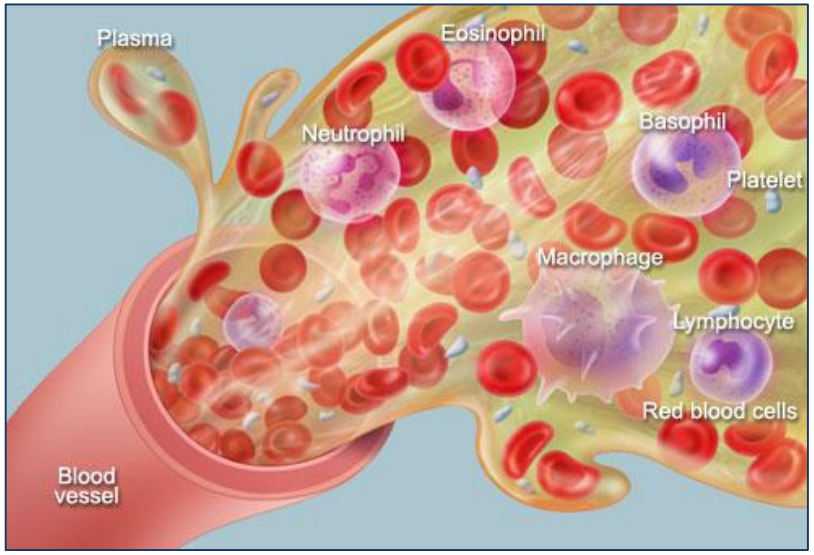
Standards Applicable to the Collection of Plasma Suitable for Fractionation



Lesley Bust, WPBTS, South Africa

Contents

- *General Requirements*
- *Source Material*
- *Plasma Collection*
- *Blood Containers*
- *Plasma Processing*
- *Testing*
- *Transport & Storage*
- *Definition of Standards*

General Requirements

- Plasma supplier to be licenced & accredited
- Suitable premises for collection, processing & testing
- Appropriate equipment which is calibrated, validated, maintained & checked
- GMP followed in processes and control
- Qualified and competent personnel

Source Material

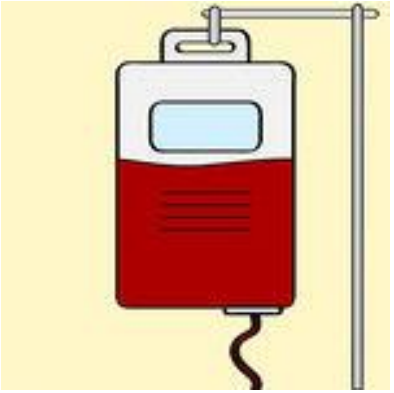
- Only plasma of human origin
- Expired FFP may be acceptable up to 2 years
- Malaria plasma acceptable for fractionation
- Plasma not required to be group specific

Plasma Collection

- From healthy donors who meet normal criteria
- By Whole Blood donation or plasmapheresis
- Aseptic conditions, in closed system
- Donation time $\leq$ 15 mins if used for clotting factors
- Plasma volume of $\geq$ 200 ml generally required

Blood Containers

- Materials approved/licenced in country and/or comply with international standard eg. CE mark
- Suitable anti-coagulant
- Segments barcoded with same number as donation
- Sufficient pilot tube samples of required size
- Bag labels kept to minimum, no handwritten numbers

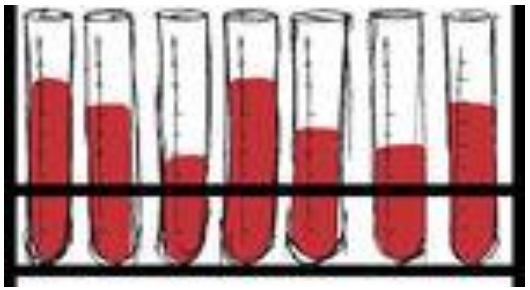


Plasma Processing

- Plasma separated from Whole Blood using aseptic technique
- Frozen to below –25 °C within 24 hours after collection
- Frozen flat with uniform thickness
- Validated shock freezing system used (max freezing time of 45 minutes)
- Lipaemic, haemolysed & red cell-contaminated units removed

Testing

- Blood donations individually tested
- Test systems approved by international body & validated
- Controls used with each run
- All donations non-reactive or negative for viral markers
- No abnormal antibodies of clinical significance
- FVIII not less than 0,7 IU/ml if used for clotting factors
- Internationally accepted EQA/proficiency programme
- Look-back system to trace previous donations



Transport & Storage

- Plasma transported in dry ice, refrigerated containers or insulated boxes
- Temperature during storage & transit to remain below minus 20 °C
- Optimal storage temperature for plasma is at minus 25 °C for up to 36 months
- Cold chain system to be validated

Definition of Standards

- Where should required standards be defined?
- Various possibilities:
  - Fractionator specifications
  - Supplier and Fractionator contract
  - Common international regulations
  - WHO document*
  - Standards of Practice, local and international

** WHO Recommendations for Production, Control & Regulation of Human Plasma for Fractionation*

Conclusion

- Collecting facility needs to understand specific needs & requirements of Fractionator
- Fractionator to perform initial & regular supplier audits
- Supplier to inform Fractionator of any significant changes
- Ultimately need collaboration to produce quality products that will meet needs of clinicians and patients

Thank You !