Standard Operating Procedure (SOP)

Comparison of Donor Eligibility and Plasma Handling Criteria for IVD Use vs. Therapeutic Fractionation

1. Purpose

This SOP outlines the differences in donor selection, regulatory requirements, and handling protocols for plasma collected for in vitro diagnostic (IVD) use versus plasma collected for therapeutic fractionation. It also clarifies Drumlin Plasma's scope of operations within this framework.

2. Scope

This SOP applies to all personnel involved in donor screening, plasma collection, labeling, storage, and distribution at Drumlin Plasma. It is also intended to inform external stakeholders of the standards and criteria used in IVD-specific plasma collection.

3. Definitions

• IVD Plasma: Plasma used to manufacture or validate diagnostic tests. Not intended for reinfusion into patients.

• Therapeutic Plasma: Plasma collected for manufacturing plasma-derived medicinal products (e.g., IVIG, albumin, clotting factors) intended for patient transfusion.

• Source Plasma: Plasma collected through apheresis for either IVD or therapeutic purposes.

4. IVD-Specific Considerations

- Disease-State Donors: Individuals with conditions like rheumatoid arthritis, lupus, or hemophilia provide valuable plasma for assay calibration and validation.
- Marker Positivity: Clients often require plasma that is positive for specific biomarkers (e.g., RF+, HIV+, ANA+). This is a core difference from therapeutic criteria.
- Protein Factor Levels: Some IVD applications require donors with high or low concentrations of specific clotting or immunological proteins.
- Flexible Eligibility: Drumlin accepts donors based on the diagnostic value of their plasma, even if they would be excluded from therapeutic donation.
- Labeling and Documentation: All IVD plasma is clearly labeled as not for human use, and includes disease-specific metadata when applicable.
- Custom Handling Protocols: Clients may require specialized freezing, aliquoting, or shipping instructions to preserve diagnostic targets.

5. Key Differences: IVD vs. Therapeutic Use

Category	IVD Plasma	Therapeutic Plasma
End Use	Diagnostic test manufacturing and validation	Injectable therapies for direct patient treatment
Regulatory Oversight	Not subject to full blood regulations; follows biospecimen export rules	Regulated under Health Canada Blood Regulations and FDA/EMA standards
Licensing Requirement	No Blood Establishment License (BEL) required	Requires BEL or equivalent regulatory licensing
Donor Eligibility	Flexible; includes disease-state donors. Not as restrictive on medications being taken, travel or the 2 donations minimum for therapeutic use	Strict; healthy donors only
Marker Status	Not as restrictive since it is for IVD use only. Positive markers may actually be desirable for certain diagnostics	Requires negative screening for transmissible diseases
Protein Factor Levels	May be required to match assay development needs	Standardized; usually not a selection criterion
Pathogen Reduction	Not required; plasma not reinfused	Implemented during fractionation
Labeling Requirements	Must state "For IVD Use Only"	Requires full traceability and GMP labeling
Storage & Handling	Customized to client needs (e.g., aliquots, -80°C)	Strict GMP-compliant chain of custody and conditions

6. Drumlin Plasma's Position

Drumlin Plasma collects and supplies plasma exclusively for in vitro diagnostic and research purposes. We do not supply plasma for therapeutic use and are not licensed as a blood establishment. However, our Quality Management System (QMS) is designed to align with best practices from Health Canada's Blood Regulations and FDA guidance, particularly with respect to traceability, donor safety, and quality controls.

7. References

- FDA CFR Title 21 Part 640
- Health Canada Guidance on Blood Regulations
- ISO 13485: Medical devices – Quality management systems
- WHO Guidelines on GMP for Blood Establishments

8. Approval and Review

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Approved by: [Insert Approver Name and Title]

Effective Date: [Insert Date]

Review Cycle: [e.g., Annual or Biannual Review]