STANDARD OPERATING PROCEDURE

Fresh Frozen Plasma (FFP) Transfusion

Blood Bank and Transfusion Service

Version: 1.1

Effective Date: 2026 APRIL

Review Date: 2027 APRIL

Approved by: Pathology Department

1. Purpose

To ensure safe preparation, storage, thawing, compatibility, and appropriate laboratory use of Fresh Frozen Plasma (FFP).

2. Scope

This SOP applies to all laboratory personnel involved in:

- Preparation of FFP
- Storage and monitoring
- Thawing and issue
- Documentation

3. Responsibility

Role	Responsibility
Pathologist / Transfusion Specialist	Overall supervision and policy approval
Medical Laboratory Technologist	Component preparation, verification, thawing, and issue
Laboratory Technician	Processing, storage, labeling, monitoring, and documentation

4. Definitions

Fresh Frozen Plasma (FFP): Plasma separated from whole blood and frozen within a specified time to preserve coagulation factors.

5. Procedure

5.1 Preparation of Fresh Frozen Plasma

FFP shall be prepared from **whole blood collected in anticoagulant-preservative solution**.

Preparation Steps

- Centrifuge whole blood at **1-6°C under validated conditions**
- Use **heavy (hard) spin** to separate plasma from cellular components:
  - Heavy spin, with a temperature setting of **4°C**
  - Using **5000 × g for 5 minutes** or **5000 × g for 7 minutes** (plus deceleration time)
- To calculate RPM for the centrifuge, the following formula is used:

```
RCF = 28.38 × R × (RPM/1000)²
or
RPM = √[RCF / (28.38 × R)] × 1000
```

RCF = relative centrifugal force (× g); R = radius in inches; RPM = revolutions per minute

- Express plasma into a satellite bag using a **plasma extractor**
- Seal tubing and maintain a **closed system**

Freezing Requirements

- Plasma must be **frozen within 6-8 hours of collection**
- Freeze rapidly to preserve clotting factors

Labelling and Documentation

- Ensure proper labeling (donor ID, date/time, component type)
- Maintenance of a **closed system**

5.2 Storage of FFP

- Store FFP in a **deep freezer at ≤ -18°C**
  - Lower temperatures (e.g., ≤ -30°C) are preferred where available
- **Shelf life:** Up to 1 year at ≤ -18°C

- Maintain:
  - Continuous temperature monitoring
  - Regular temperature recording
- Units must be properly labeled and traceable

5.3 Thawing of FFP

Thaw FFP **only when required for transfusion**.

Thawing Procedure

- Use a **water bath or plasma thawer at 30-37°C**
- Ensure protective covering of the unit
- Avoid direct contact with water (prevent contamination)

Post-Thawing Inspection

- Check for **leakage, clots, or abnormal appearance**
- Do not refreeze thawed plasma

5.4 Compatibility

- Crossmatch is **not required** for FFP
- ABO compatibility is **required/preferred**:
  - Use plasma compatible with recipient's red cells
- Rh compatibility:
  - Not essential, but Rh-negative preferred for Rh-negative females of childbearing age

5.5 Clinical Indications

FFP should be used for coagulation factor deficiency with bleeding or risk of bleeding.

Indications

- Active bleeding with coagulopathy
- Disseminated intravascular coagulation (DIC)
- Massive transfusion with coagulopathy
- Liver disease with bleeding

- Warfarin reversal with bleeding (if factor concentrate unavailable)
- Plasma exchange (e.g., TTP)

Not Indicated For

- Volume expansion
- Nutritional support
- Mild abnormal coagulation tests without bleeding

5.6 Dose

- Recommended dose: **10-15 mL/kg body weight**
- Adjust based on clinical condition and coagulation results

5.7 Issue and Handling of FFP

Before Issue

- Verify patient identity (two identifiers)
- Check ABO compatibility
- Check unit number and expiry
- Inspect unit for damage or abnormality

At Issue

Record the following information:

- Patient details
- Unit number
- Date and time
- Staff signature

After Issue

- Transfuse **as soon as possible after thawing**
- Complete transfusion within **30-60 minutes** (as per local policy)

5.8 Post-Issue / Return

Thawed FFP should **not be returned to frozen storage**.

A unit may be returned to controlled storage **only if ALL conditions are met**:

- The unit has **not been transfused or entered**
- The unit has been maintained under **controlled conditions**
- The unit is within **validated institutional time limits**
- The unit is **visually acceptable**
- The unit identity and labeling are intact

Discard the unit if:

- Storage conditions are compromised
- Unit is expired
- Evidence of contamination, leakage, or abnormal appearance
- Time outside controlled conditions exceeds defined policy

6. Quality Control and Assurance

- Maintain:
  - Continuous temperature monitoring (freezer and thawing equipment)
  - Traceability of each unit
  - Complete documentation
- Perform:
  - Regular equipment calibration and validation
- Participate in:
  - Quality assurance programs
  - Proficiency testing

7. Safety Precautions

- Use PPE at all times
- Treat all blood products as potentially infectious
- Follow biosafety and waste disposal procedures

8. Documentation

Maintain records of:

- Donor and unit details
- Preparation records
- Storage logs
- Thawing records
- Issue register
- Discard records

9. References

1. AABB Standards for Blood Banks and Transfusion Services (latest edition)
2. AABB Technical Manual (latest edition)
3. Guidelines for Blood Transfusion Service, MOHS, Myanmar, 2018

> ***Audit Statement:*** *This SOP is based on AABB standards and aligned with MOHS guidelines where applicable.*