

INSTRUCTIONS FOR USE

IntelliFlow™

Platelet Stabilization Tube

Product Name	Platelet Stabilization Tube
Catalog Number	ZK202601
Package Size	50 tubes per pack
Regulatory Status	For Research Use Only. Not for use in diagnostic procedures.

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

1. INTENDED USE

The Platelet Stabilization Tube is a laboratory sample preparation reagent containing a proprietary platelet stabilization solution. It is designed to preserve platelets' basal activation status as it exists at the time of sample collection, protecting against the artifactual activation that begins once platelets leave the body, for up to 7 days at either room temperature (72-82°F / 22-28°C) or refrigerated (36-46°F / 2-8°C) conditions.

The tube is intended for use as a post-collection sample stabilization container for downstream flow cytometric analysis of platelet activation markers and surface glycoproteins in research applications.

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2. PRINCIPLE OF THE PROCEDURE

Once platelets leave the body, they begin to activate spontaneously. Under standard collection and storage conditions (3.2% sodium citrate tubes at 72-82°F (22-28°C) or 36-46°F (2-8°C)), the percentage of CD62P-positive (activated) platelets increases substantially within hours, rendering samples unsuitable for accurate assessment of in vivo platelet activation status.

The Platelet Stabilization Tube contains a proprietary stabilization solution that inhibits further ex vivo platelet activation following specimen transfer into the tube. Samples transferred into the tube maintain their platelet activation profile, as measured by CD62P expression, for up to 7 days under either ambient or refrigerated storage.

Preserved samples can subsequently be analyzed using standard flow cytometry protocols on any commercially available flow cytometer, with antibodies from any major vendor.

REAGENTS

Each Platelet Stabilization Tube contains a proprietary platelet stabilization solution (0.5 mL, pre-filled). The stabilization solution is supplied ready to use. Do not dilute or add other components to the tube.

3. MATERIALS PROVIDED

Each package contains:

- Platelet Stabilization Tubes (standard vacuum tube format)
- Instructions for Use

Tube specifications:

- Format: Standard vacuum tube
- Material: Laboratory-grade glass
- Closure: Red cap
- Additive: Proprietary platelet stabilization solution (0.5 mL pre-filled)

- Vacuum: Calibrated to receive 0.5 mL of transferred specimen (specimen-to-stabilization solution ratio 1:1)
- Transfer volume: 0.5 mL
- Label: Product identification, lot number, expiration date
- Outer diameter: 8 ±0.5 mm
- Length: 75 ±2.0 mm

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Standard 3.2% sodium citrate collection tubes (for initial venipuncture)
- Specimen transfer device (not included)
- Standard flow cytometry reagents and antibodies (compatible with major vendors including BD Biosciences and Beckman Coulter)
- Flow cytometer (any commercially available instrument)

5. STORAGE AND STABILITY

Unopened product (before use):

- Store at room temperature (72°F to 82°F / 22°C to 28°C)
- Transport: 15-30°C (59-86°F)
- Shelf life: 24 months from date of manufacture
- Do not freeze
- Protect from direct sunlight
- Use before the expiration date printed on the label

After sample transfer:

- Store at either room temperature (approximately 72-82°F / 22-28°C) or refrigerated (approximately 36-46°F / 2-8°C)
- Samples remain stable for up to 7 days under either condition
- No cold chain required for shipping
- Do not freeze samples after transfer

INDICATIONS OF PRODUCT DETERIORATION

Do not use the Platelet Stabilization Tube if any of the following are observed in an unfilled tube:

1. Cloudiness or visible precipitate in the stabilization solution.
2. Discoloration of the stabilization solution.
3. Loss of vacuum (tube fails to receive the stated transfer volume).
4. Visible cracks, chips, or damage to the glass tube.

If any indication of product deterioration is observed, do not use the tube. Contact IntelliFlow Tech LLC Technical Support at intelliflowtech@gmail.com or 1-818-278-9388.

FREEZING AND THAWING

Samples in the Platelet Stabilization Tube:

1. Do not freeze samples stored in the Platelet Stabilization Tube. Freezing will cause hemolysis and compromise sample integrity.
2. If downstream analysis requires frozen plasma, centrifuge the sample first to obtain plasma, then transfer the plasma fraction to a separate labeled cryogenic tube prior to freezing.
3. Plasma may be stored frozen at -4°F (-20°C) or -112°F (-80°C) for long-term storage. Thaw at 36-46°F (2-8°C) and mix gently before use. Follow the downstream assay manufacturer's instructions for processing.

6. SPECIMEN COLLECTION AND HANDLING

⚠ VACUUM NOTICE: The tube is calibrated with negative pressure for automatic suction during transfer. Do not open the cap prior to transfer — vacuum loss will result in incorrect fill volume and unreliable results.

Step 1 — Specimen Collection

Collect venous specimen into a standard 3.2% sodium citrate vacuum collection tube using standard venipuncture technique for research specimen collection. Ensure the tube is filled to its specified volume and gently inverted 5 to 8 times to mix with anticoagulant.

Step 2 — Sample Transfer

Within 5 minutes of collection, use a specimen transfer device to transfer specimen from the citrate collection tube into the Platelet Stabilization Tube. Allow the vacuum to receive exactly 0.5 mL of transferred specimen until filling stops. Do not overfill.

Step 3 — Mixing

Gently invert the Platelet Stabilization Tube 5 to 8 times to ensure thorough mixing of the specimen with the stabilization solution. Do not shake.

Step 4 — Storage

Store the Platelet Stabilization Tube at either room temperature (72-82°F / 22-28°C) or refrigerated (36-46°F / 2-8°C) until analysis. Samples remain stable for up to 7 days under either condition.

Step 5 — Analysis

At any point within the 7-day window, process the stored sample according to standard flow cytometry protocols for platelet marker analysis. No special pretreatment is required beyond standard sample preparation steps.

7. PERFORMANCE CHARACTERISTICS

Stability of CD62P expression in the Platelet Stabilization Tube (n = 10 healthy donors)

Specimens were collected from healthy donors into standard 3.2% sodium citrate tubes and transferred into Platelet Stabilization Tubes. CD62P-positive platelet percentages were measured at 0 hours, 6 hours, Day 3, Day 5, and Day 7, under both 72-82°F (22-28°C) and 36-46°F (2-8°C) storage conditions.

Time Point	72-82°F / 22-28°C (% CD62P+)	36-46°F / 2-8°C (% CD62P+)
0 hour	1.3	1.3
6 hours	1.1	1.2
Day 3	1.5	1.2
Day 5	1.4	1.2
Day 7	1.5	1.2

Standard deviation across all time points: < 2%. These findings are provided for research reference only and do not constitute a diagnostic performance claim.

Comparison to standard citrate tubes (same donors, identical conditions):

Time Point	Standard Citrate 72-82°F / 22-28°C	Standard Citrate 36-46°F / 2-8°C
0 hour	4.8	4.8
6 hours	18.7	17.4

Day 3	22.7	33.1
Day 5	27.8	44.7
Day 7	41.4	65.1

Under standard citrate storage, CD62P-positive platelets reached 41.4% (72-82°F / 22-28°C) and 65.1% (36-46°F / 2-8°C) by Day 7, showing a substantial increase in CD62P levels over the same period. Under Platelet Stabilization Tube storage, CD62P levels remained at or below 1.5% throughout the 7-day period under both temperature conditions.

Compatibility

The Platelet Stabilization Tube is a standardized product with one specification. It has been validated for use with flow cytometry reagents from major vendors including BD Biosciences and Beckman Coulter. It is compatible with all commercially available flow cytometers following standard sample preparation protocols. No vendor-specific customization or protocol modification is required.

8. LIMITATIONS

- For Research Use Only. Not for use in diagnostic procedures.
- Performance data has been established using samples from healthy donors. Performance in samples from subjects with underlying platelet abnormalities, active coagulopathy, or anticoagulant therapy has not been independently validated.
- The product is designed to preserve platelets' basal activation status for analysis of activation markers (e.g., CD62P) and platelet surface glycoproteins, protecting against the artifactual activation that begins once platelets leave the body. If agonist stimulation is required as part of the research protocol, agonist must be added to citrate-anticoagulated specimen prior to transfer into the Platelet Stabilization Tube.
- Specimen should be transferred from the collection tube into the Platelet Stabilization Tube within 5 minutes of specimen collection, in accordance with standard flow cytometry pre-analytical practices.
- Overfilling or underfilling will result in an incorrect specimen-to-additive ratio and may lead to suboptimal product performance. The vacuum is calibrated to receive exactly 0.5 mL of transferred specimen.
- Do not reuse the tube or its contents.

9. WARNINGS AND PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. Do not use tubes past the expiration date printed on the label.
3. Do not transfer specimen into the Platelet Stabilization Tube past the expiration date. If sample transfer occurs on or before the expiration date, samples should be processed within the stated stability window.
4. Do not use tubes for collection of materials to be injected into humans. Do not use the Platelet Stabilization Tube for direct venous specimen collection.
5. Product is intended for use as supplied. Do not dilute or add other components to the tube.
6. Overfilling or underfilling of tubes will result in an incorrect specimen-to-additive ratio and may lead to suboptimal product performance.
7. Store as directed. Improper storage may affect product performance.
8. Treat all samples as potentially biohazardous. Follow universal precautions and institutional biosafety guidelines.
9. Use personal protective equipment (gloves, lab coat, eye protection) during sample handling.
10. Dispose of used tubes and associated materials as biohazardous waste in accordance with local, state, and federal regulations.
11. Do not use if the tube is damaged, cracked, or has lost its vacuum.

CAUTION — GLASS TUBE HANDLING

- a. Glass has the potential for breakage. Precautionary measures should be taken during all handling, transport, and storage of glass tubes.
- b. All biological specimens and materials coming into contact with them should be treated as potentially biohazardous and capable of transmitting infection. Dispose of in accordance with applicable federal, state, and local regulations. Avoid contact with skin and mucous membranes.
- c. Used tubes and associated materials should be disposed of as infectious medical waste.
- d. To remove the stopper, gently rock it from side to side, or grasp with a simultaneous twisting and pulling action. A thumb-roll procedure for stopper removal is NOT recommended as tube breakage and injury may result.
- e. Safety Data Sheet (SDS) can be obtained by contacting IntelliFlow Tech LLC at intelliflowtech@gmail.com or 1-818-278-9388.

10. DISPOSAL

Used tubes containing samples should be disposed of as biohazardous waste in accordance with local, state, and federal regulations.

11. REGULATORY STATUS

- United States: For Research Use Only. Not for use in diagnostic procedures.

REFERENCES

#	Reference
1	Clinical and Laboratory Standards Institute (CLSI). Enumeration of Immunologically Defined Cell Populations by Flow Cytometry. CLSI Standard H42. Wayne, PA: CLSI.
2	Clinical and Laboratory Standards Institute (CLSI). Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations. 1st ed. CLSI guideline PRE04. Wayne, PA: CLSI; 2023.

12. SYMBOLS USED ON LABELING

Symbol	Meaning
REF	Catalog number
LOT	Batch code
Hourglass icon	Use by date (expiration)
Factory icon	Manufacturer
Thermometer icon	Storage temperature range
RUO	Research Use Only

ORDERING INFORMATION

Field	Information
Distributor	IntelliFlow Tech LLC

Address	16192 Coastal Highway, Lewes, DE 19958, United States
Email	intelliflowtech@gmail.com
Phone	1-818-278-9388
Catalog Number	ZK202601
Package Size	50 tubes per pack

13. MANUFACTURER AND DISTRIBUTOR INFORMATION

Manufactured in China by:

Jiangsu Maik Medical Apparatus Co Ltd

No 59, JiangShen Road, Jiangyan District, Taizhou City, China 225500

Distributed in the United States by:

IntelliFlow Tech LLC

16192 Coastal Highway, Lewes, DE 19958, United States

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14. DOCUMENT INFORMATION

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