INSTRUCTIONS FOR USE

IntelliFlow™ Platelet Stabilizer

Product Name	Platelet Stabilizer
Catalog Number	ZK202605
Package Size	50 vials 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 Stabilizer 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 Platelet Stabilizer 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 Stabilizer contains a proprietary stabilization solution that inhibits further ex vivo platelet activation following specimen transfer into the Platelet Stabilizer. Samples transferred into the Platelet Stabilizer 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 Stabilizer 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 Platelet Stabilizer.

3. 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

Do not use the Platelet Stabilizer if any of the following are observed in an unfilled vial: cloudiness or visible precipitate in the stabilization solution; discoloration of the stabilization solution; liquid level below the stated fill volume, or evidence of leakage; visible cracks, chips, or damage to the glass vial. If any indication of product deterioration is observed, do not use the Platelet Stabilizer. Contact IntelliFlow Tech LLC Technical Support at intelliflowtech@gmail.com or 1-818-278-9388.

4. SPECIMEN COLLECTION AND HANDLING

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 calibrated pipette to add 0.5 mL of specimen from the citrate collection tube to the Platelet Stabilizer.

Step 3 — Mixing

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

Step 4 — Storage

Store the Platelet Stabilizer 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.

5. PERFORMANCE CHARACTERISTICS

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

Specimens were collected from healthy donors into standard 3.2% sodium citrate tubes and transferred into Platelet Stabilizers. 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 Stabilizer storage, CD62P levels remained at or below 1.5% throughout the 7-day period under both temperature conditions.

6. 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 Stabilizer.

- Specimen should be transferred from the collection tube into the Platelet Stabilizer 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.
- Do not reuse the vial or its contents.

7. WARNINGS AND PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. Do not use vials past the expiration date printed on the label.
3. Do not transfer specimen into the Platelet Stabilizer 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 vials for collection of materials to be injected into humans. Do not use the Platelet Stabilizer for direct venous specimen collection.
5. Product is intended for use as supplied. Do not dilute or add other components to the Platelet Stabilizer.
6. Overfilling or underfilling of vials 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 vials and associated materials as biohazardous waste in accordance with local, state, and federal regulations.
11. Do not use if the vial is damaged, cracked, or leaking.

STATEMENT OF WARNINGS

DANGER

Formaldehyde (CAS 50-00-0) 0.1 – 1%
Glutaraldehyde (CAS 111-30-8) 0.1 – 1%

Harmful if swallowed, in contact with skin or if inhaled.
May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause cancer.
Avoid breathing vapours.
Wear protective gloves, protective clothing and eye/face protection.
In case of inadequate ventilation, wear respiratory protection.
IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
If skin irritation occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Safety Data Sheet is available from IntelliFlow Tech LLC at intelliflowtech@gmail.com or 1-818-278-9388.

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.

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	ZK202605
Package Size	50 vials per pack

8. MANUFACTURER AND DISTRIBUTOR INFORMATION

Manufactured in China by:
Jiangsu Maik Medical Apparatus Co., Ltd.
No. 59, Jiangshen Road, Jiangyan District, Taizhou City, Jiangsu Province, China 225500

Distributed in the United States by:
IntelliFlow Tech LLC
16192 Coastal Highway, Lewes, DE 19958, United States
Email: intelliflowtech@gmail.com
Tel: 1-818-278-9388

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