INSTRUCTIONS FOR USE

IntelliFlow™

Leukocyte Stabilization Tube

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

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1. INTENDED USE

The Leukocyte Stabilization Tube is a laboratory sample preparation reagent containing the anticoagulant K2EDTA and a proprietary leukocyte stabilization solution. It is designed to preserve leukocyte surface antigen integrity in samples for up to 22 days: room temperature (72–82°F / 22–28°C) for Days 1–7, then refrigerated (36–46°F / 2–8°C) through Day 22.

The tube is intended for use as a post-collection sample stabilization container for downstream multi-color flow cytometric analysis of lymphocyte immunophenotypes including T cells, B cells, and NK cells in research applications.

Specimen transfer only. For Research Use Only. Not for use in diagnostic procedures.

2. PRINCIPLE OF THE PROCEDURE

Once the specimen is collected, leukocyte surface antigens begin to degrade over time. Under standard collection and storage conditions without stabilization (EDTA anticoagulant tubes at 72~82°F (22~28°C) or 36~46°F (2~8°C)), specimens must be processed within 48 hours — making remote sample collection and batched laboratory analysis difficult.

The Leukocyte Stabilization Tube contains a proprietary stabilization solution that stabilizes leukocyte surface antigens following specimen transfer into the tube. Leukocyte surface antigens including CD3, CD4, CD8, CD19, and CD16/CD56 remain stable for up to 22 days under the specified storage conditions.

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 Leukocyte Stabilization Tube contains the anticoagulant K2EDTA and a proprietary leukocyte stabilization solution (20 µL pre-filled). At a 1:100 stabilization solution-to-sample ratio, each tube is calibrated to receive 2 mL. The stabilization solution is supplied ready to use. Do not dilute or add other components to the tube.

3. MATERIALS PROVIDED

Each package contains:

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

Tube specifications:

- Format: Standard vacuum tube (post-collection specimen stabilization container; not for direct specimen collection)
- Material: glass
- Closure: Blue cap
- Additive: K2EDTA anticoagulant and proprietary leukocyte stabilization solution (20 µL pre-filled)
- Vacuum: Calibrated for vacuum-assisted post-collection transfer of 2 mL from a primary EDTA anticoagulant collection tube, maintaining a predefined 1:100 stabilization solution-to-sample ratio. The vacuum design (1) protects the operator from the stabilization solution, (2) ensures precise quantitative transfer, and (3) maintains a closed system for specimen integrity.
- 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 EDTA anticoagulant collection tubes (for initial specimen collection)
- Transfer device (for transfer into the Leukocyte Stabilization Tube)
- 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 (59–86°F / 15–30°C)
- 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:

- Days 1–7: Store at room temperature (72–82°F / 22–28°C)
- Days 8–22: Transfer to refrigerated storage (36–46°F / 2–8°C)
- Samples remain stable for up to 22 days under this two-phase storage protocol
- No cold chain required for shipping during the first 7 days
- Do not freeze samples after transfer

INDICATIONS OF PRODUCT DETERIORATION

Do not use the Leukocyte 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 or receives significantly less than 2 mL during transfer).
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 / 1-984-528-9102.

FREEZING AND THAWING

Samples in the Leukocyte Stabilization Tube:

1. Do not freeze samples stored in the Leukocyte 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

⚠ WARNING: Specimen transfer only. Direct venipuncture into the Leukocyte Stabilization Tube is strictly prohibited. This product is for Research Use Only and must not be used for direct specimen collection.

⚠ 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 the venous specimen into a standard EDTA anticoagulant 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

As soon as possible following collection, ideally within 2 hours of specimen collection, use a transfer device to transfer the specimen from the EDTA collection tube into the Leukocyte Stabilization Tube. The vacuum is calibrated for quantitative post-collection transfer of 2 mL. Transfer until filling stops. Do not overfill.

Step 3 — Mixing

Immediately after transfer, gently invert the Leukocyte 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 Leukocyte Stabilization Tube according to the following storage protocol: for Days 1 through 7, store at either room temperature (72–82°F / 22–28°C) or refrigerated (36–46°F / 2–8°C); from Day 8 through Day 22, transfer to and maintain refrigerated storage (36–46°F / 2–8°C). Samples remain stable for up to 22 days under this storage protocol.

Step 5 — Analysis

At any point within the 22-day stability window, process the stored sample according to standard flow cytometry protocols for lymphocyte immunophenotyping. No special pretreatment is required beyond standard sample preparation steps.

7. PERFORMANCE CHARACTERISTICS

Multiple studies using human peripheral specimens have demonstrated stable multicolor flow cytometric lymphocyte immunophenotyping results over 22 days in the Leukocyte Stabilization Tube (SD < 1.0% across all subsets, n=20).

Compatibility

The Leukocyte 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

1. For Research Use Only. Not for use in diagnostic procedures. Specimen transfer only. Direct venipuncture into this tube is strictly prohibited.

2. Specimen should be transferred from the collection tube into the Leukocyte Stabilization Tube ideally within 2 hours of specimen collection.

3. Overfilling or underfilling will result in an incorrect specimen-to-additive ratio and may lead to suboptimal product performance. The vacuum is calibrated for quantitative post-collection transfer of exactly 2 mL.

4. Do not reuse the tube or its contents.

9. WARNINGS AND PRECAUTIONS

1. For Research Use Only. Not for use in diagnostic procedures.

2. Specimen transfer only. Direct venipuncture is strictly prohibited. This product must not be used as a primary specimen collection device.

3. Do not open the cap prior to transfer. The tube vacuum is calibrated for automatic suction; opening the cap will result in vacuum loss and unreliable fill volume.

4. Do not use tubes past the expiration date printed on the label.

5. Do not use tubes for collection of materials to be injected into humans. This tube is a post-collection specimen stabilization reagent; it is intended for specimen transfer only. Direct venipuncture is strictly prohibited.

6. Product is intended for use as supplied. Do not dilute or add other components to the tube.

7. Overfilling or underfilling of tubes will result in an incorrect specimen-to-additive ratio and may lead to suboptimal product performance.

8. Store as directed. Improper storage may affect product performance.

9. Treat all samples as potentially biohazardous. Follow standard laboratory biosafety procedures.

10. Use personal protective equipment (gloves, lab coat, eye protection) during sample handling.

11. Dispose of used tubes and associated materials as biohazardous waste in accordance with local, state, and federal regulations.

12. Do not use if the tube is damaged, cracked, or has lost its vacuum.

CAUTION — GLASS TUBE HANDLING

- Glass has the potential for breakage. Precautionary measures should be taken during all handling, transport, and storage of glass tubes.
- 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.
- Used tubes and associated materials should be disposed of as biohazardous waste.
- 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.
- Safety Data Sheet (SDS) can be obtained by contacting IntelliFlow Tech LLC at intelliflowtech@gmail.com or 1-818-278-9388 / 1-984-528-9102.

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

1. Canonico B, Zamai L, Burattini S, et al. Evaluation of leukocyte stabilisation in TransFix-treated blood samples by flow cytometry and transmission electron microscopy. J Immunol Methods. 2004;295(1-2):67-78. PMID: 15627612.

2. Maecker HT, McCoy JP, Nussenblatt R. Standardizing immunophenotyping for the Human Immunology Project. Nat Rev Immunol. 2012;12(3):191-200. PMID: 22343568.

12. SYMBOLS USED ON LABELING

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

ORDERING INFORMATION

Field	Information
Product Name	Leukocyte Stabilization Tube
Catalog Number	ZK202602
Package Size	50 tubes per pack
Regulatory Status	For Research Use Only. Not for use in diagnostic procedures.

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:

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