TransFix® / EDTA Vacuum Blood Collection Tubes US IVD

CYTOMARK

INSTRUCTIONS FOR USE – For Rx Use Only

Intended Use

TransFix/EDTA Vacuum Blood Collection Tubes (TVTs) are intended for collection and storage of human whole blood specimens for immunophenotyping of white blood cells by flow cytometry. Recovery of lymphocyte subset markers can be accomplished over a 14-day period following collection.

TVTs are *in-vitro* diagnostic medical devices.

Summary and Principles

Immunophenotyping by flow cytometry provides a rapid and accurate assessment of the frequency and type of leukocytes in a blood sample. Any delay in testing the sample, such as transport from the collection site to analysis location, can have a negative impact on results. Sample preservation provides a solution which addresses delays between sample collection and testing.

TVTs consist of purple capped polyethylene terephthalate tubes that are designed for direct-draw blood collection. TVTs contain a solution of TransFix and K_3EDTA at the correct volume to simultaneously stabilize and anti-coagulate human whole blood at the point of collection.

Subsets of leukocytes can be distinguished by cell surface antigens using fluorescent antibodies and flow cytometry. Qualitative and quantitative changes in leukocyte subsets are used to identify and monitor immunodeficiency and hematological diseases [1]. The TransFix stabilizer acts by preserving the cell surface antigens of lymphocyte subsets until processing and analysis can be performed.

TVTs are available as a 3ml final draw volume tube. The vacuum contained within the TVT ensures that the TransFix reagent is administered at the correct ratio of 1 part TransFix to 5 parts whole blood (1:5). TVTs are sterilized by gamma radiation.

Reagents

TVTs contain TransFix and the anticoagulant, K3EDTA. TransFix is a clear green liquid containing formaldehyde and other chemicals.

Disposal

TVTs contains formaldehyde which should be disposed of in accordance with local regulations. Avoid disposing into drainage systems and the environment. Once the TVT contains a biological sample it must be considered an 'Absolute Hazard' and disposal is in accordance with local regulations regarding clinical waste.

Precautions and Warnings

1. TVTs are intended for use as specified in this document. They are *in-vitro* diagnostic medical devices for professional use only.
2. **Under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.**
3. Do not freeze the TVTs, or blood specimens collected in TVTs. Incubation times or temperatures other than those specified may lead to erroneous results.
4. Do not use TVTs after the expiration date on the tubes and packaging.
5. Only use TVTs to collect human whole blood specimens. Do not use tubes for collection of materials to be injected into patients.
6. Do not dilute or add other components to TVTs.
7. TVTs should only be used by trained phlebotomists.
8. Do not transfer specimens that have been collected in other tubes or specimens treated with other preservatives / anticoagulants into TVTs.
9. Do not use cell viability stains on blood collected in TVTs as they are fixed instantaneously.
10. Do not re-use TVTs.
11. TransFix treated blood and all materials coming into contact with it should be handled as if capable of transmitting infection.
12. Avoid contact of TransFix and TransFix treated blood samples with the skin and mucous membranes. The cell preservative is an irritant and any contact should be washed off with soap and water immediately.
13. TransFix does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
14. SDS can be obtained at www.cytomark.co.uk or by calling +44(0)1280 827460.

Prevention of Backflow

Since TVTs contain chemical additives, it is important to avoid possible backflow from the tube. To guard against backflow:

1. Keep patient's arm in the downward position during the collection procedure.
2. Hold the tube with the cap in the uppermost position so that the tube contents do not touch the stopper in the cap or the end of the needle during sample collection.
3. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
4. Tube contents should not touch stopper in cap or the end of the needle during collection.

Indications of Deterioration in unused TVTs

1. Cloudiness or precipitate visible in the TransFix.
2. Color change of TransFix from a clear green liquid.
3. TransFix change from liquid to solid.
4. If indications of product deterioration occur, do not use TVTs and contact Cytomark immediately on: +44(0)1280 827460 or support@cytomark.co.uk.

Storage Conditions and Stability

All TransFix products are shipped at ambient temperature (2 - 25°C). Additional insulation may be required for shipment during extreme temperature conditions. TVTs are supplied in a sealed foil pouch.

Tubes in an unopened or opened pouch must be stored at 2 - 8°C until the expiration date on the label.

Instructions for Use

1. Collect blood by venipuncture according to normal phlebotomy practice. TVTs are compatible with shielded needle devices from most major manufacturers.
2. Fill tube completely. Blood will be aspirated up to the correct total volume and no further. This is important to avoid an incorrect TransFix to blood ratio that could affect results.
3. Remove the TVT from the needle holder and **immediately mix by gentle inversion 10 times** to distribute the TransFix throughout the blood sample. Inadequate or delayed mixing may result in coagulation and inaccurate test results. Do not vortex.
4. After collection, store/transport the blood filled TVT at 2 - 8°C for up to 14 days or for up to 3 days at 18 - 25°C.
5. If refrigerated, incubate the TVT at room temperature (18 - 25°C) for 15 minutes prior to use.
6. Mix the TransFix treated blood by rolling the TVT between the hands 10 times and by inverting 10 times. Heavier cells and blood components will sediment over the 14 day period, forming two distinct layers; this is normal.
7. Remove and reinsert the cap by grasping with a simultaneous twisting and pulling action, not by a 'thumb roll' method.
8. Perform immunophenotyping by flow cytometry in accordance with the manufacturer's instructions. A 'stain, lyse-no wash' sample preparation method is recommended. Blood stabilized within TVTs should be analyzed within 6 hours before being returned to 2 - 8°C storage for future use, if necessary.
9. **When treated with Transfix the dilution factor must be accounted for when calculating absolute cell counts. Adjust the absolute cell count by multiplying the output by 1.2.**

Notes:

1. Use caution when implementing automatic gating strategies as light scatter positions of cells stabilized by TransFix may differ from those of untreated cells.
2. Studies have shown that increased levels of hemolysis, icterus and lipemia do not affect the results.

TVTs are validated using a panel of markers including CD3, CD4, CD8, CD16/CD56, CD19 and CD45. A certificate of analysis and a certificate of conformity can be provided with every batch of TVTs and is available at www.cytomark.co.uk.

It is recommended that all antibody conjugates are validated in association with TransFix prior to use. A list of antibodies compatible with TransFix can be found at www.cytomark.co.uk.

References

1. Evaluation of stabilized blood cell products as candidate preparations for quality assessment programs for CD4 T-cell counting. Bergeron et al, Clinical Cytometry, Vol. 50, 2002, 86-91.

Ordering Information

Please call Cytomark on +44(0)1280 827460 or email support@cytomark.co.uk for assistance. Additional information can be found online at www.cytomark.co.uk.

Product Descriptions	Catalogue Numbers
TransFix/EDTA Vacuum Blood Collection Tubes (2x 3ml tube)	TVT-03-2-US
TransFix/EDTA Vacuum Blood Collection Tubes (50x 3ml tube)	TVT-03-50-US

Cytomark, a Division of Caltag Medsystems Ltd.

Caltag Medsystems Ltd, Buckingham, MK18 1TF, UK

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