# TransFix® / EDTA Vacuum Blood Collection Tubes

CE

CYTOMARK

## INSTRUCTIONS FOR USE

### 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 leucocytes in a blood sample. However, when blood is collected in routine EDTA tubes, any delay in testing, such as transport of samples from 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. They contain a solution of TransFix and $K_3$EDTA at the correct volume to simultaneously stabilise and anti-coagulate human whole blood at the time of collection. The stabiliser acts by preserving the cell surface antigens of white blood cells (leucocytes) until processing and analysis can be performed.

Subsets of leucocytes can be distinguished on the basis of cell surface antigens using fluorescent antibodies and flow cytometry. Qualitative and quantitative changes in leucocyte subsets are used to identify and monitor immunodeficiency and haematological diseases [1].

TVTs are available in two sizes: a 3ml and 9ml final draw volume tube. The vacuum contained within the TVT ensures that the TransFix/EDTA reagent is administered at the correct ratio of 1 part TransFix/EDTA to 5 parts whole blood (1:5). TVTs are sterilised by gamma radiation.

### Reagents

TVTs contain the anticoagulant, $K_3$EDTA, and the TransFix cell preservative in a liquid medium.

### Precautions and Warnings

1. TVTs are intended for use as specified in this document. They are *in-vitro* diagnostic medical devices.
2. Do not freeze the TVTs, or blood specimens collected in TVTs. Incubation times or temperatures other than those specified may lead to erroneous results.
3. Do not use TVTs after the expiration date on the tubes and packaging.
4. Only use TVTs to collect human whole blood specimens. Do not use tubes for collection of materials to be injected into patients.
5. Do not dilute or add other components to TVTs.
6. Under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
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/EDTA treated blood and all materials coming into contact with it should be handled as if capable of transmitting infection.
12. Avoid contact of TransFix/EDTA and TransFix/EDTA treated blood samples with the skin and mucous membranes. The cell preservative is considered an irritant and any contact should be washed off with soap and water immediately.
13. Product should be disposed with infectious medical waste.
14. Remove and reinsert the cap by grasping with a simultaneous twisting and pulling action, not by a 'thumb roll' method.
15. TransFix/EDTA does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
16. 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 Product Deterioration

1. Cloudiness or precipitate visible in TransFix/EDTA of unused TVTs.
2. Colour change of TransFix/EDTA from a clear green liquid in unused TVTs.
3. Reagent change from liquid to solid in unused TVTs.
4. If indications of product deterioration occur, do not use TVTs and contact Caltag Medsystems immediately on: +44(0)1280 827460 or cytomark@caltagmedsystems.co.uk.

### Storage Conditions and Stability

TVTs are supplied in a sealed foil pouch that contains a humidified environment in order to minimise the effect of TransFix/EDTA evaporation from the tubes. Tubes in an unopened pouch are stable at 2 - 8°C until the expiration date on the label. Once the pouch is opened, TVTs have a shelf life of 6 months from the date that the pouch is opened, or until the expiration date on the label. TVTs removed from an opened pouch must be used within 2 hours when at room temperature (18 - 25°C), otherwise returned to 2 - 8°C storage. Do not freeze TVTs.

### HIV Panel of Markers

The HIV panel of markers including CD3, CD4, CD8, CD16/CD56, CD19 and CD45 are stable in blood samples stored in TVTs for up to 14 days at 2 - 8°C.

### Instructions for Use

1. Collect blood by venepuncture according to CLSI document H3-A62 [2]. 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/EDTA 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/EDTA throughout the blood sample. Inadequate or delayed mixing may result in 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 4 days at 18 - 25°C. External studies have shown that TransFix can successfully stabilise blood samples at 37°C for up to 7 days [3].
5. If refrigerated, incubate the TVT at room temperature (18 - 25°C) for 15 minutes prior to use. Then mix the TransFix/EDTA-treated blood by rolling the TVT between the hands 10 times and by inverting as before.
   **Note:** Heavier cells and blood components will sediment over the 14 day period, forming two distinct layers. This is normal. Re-suspend the cells thoroughly by repeating step 5 if necessary.
6. Perform immunophenotyping by flow cytometry in accordance with the manufacturer's instructions. A 'stain, lyse-no wash' sample preparation method is recommended. Blood stabilised within TVTs should be analysed within 6 hours before being returned to 2 - 8°C storage for future use, if necessary.
   **Note:**

a. Light scatter positions of cells stabilised with TVTs may differ slightly from those of untreated cells.
b. The dilution factor must be accounted for when calculating absolute cell counts. This can be done by multiplying the value given by the manufacturer to the absolute counting beads by 1.2 so that absolute counts are automatically corrected for TransFix treated blood samples.
c. Studies have shown that moderately high levels of haemolysis, icterus and lipemia do not affect the results. Grossly haemolysed samples should be rejected.

A certificate of analysis and a certificate of conformity can be provided with every TVT batch.

### References


1. Evaluation of stabilised 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.
2. Clinical and Laboratory Standards Institute. H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venepuncture; Approved Standard—Sixth Edition.
3. Flow Cytometric Profiles, Biomolecular and Morphological Aspects of TransFixed Leukocytes and Red Cells. Barbara Canonico et al, Clinical Cytometry, Vol. 78, 2010, 267-278.


### Ordering Information

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

### Glossary of Harmonised Symbols

Catalogue No.


Use by

Batch Code


Manufacturer


Temperature Limitation

*In-vitro* Diagnostic Medical Device


Consult Instructions For Use


Do not re-use


Biological Risk


Irritant


Suspected Carcinogen

Sterile by irradiation

CE

Cytomark, a Division of Caltag Medsystems Ltd.


Caltag Medsystems Ltd, Buckingham, MK18 1TF, UK product manufactured by Vacutest KIMA s.r.l, 35020 Arzergrande (PD) Italy.

Revision 6, 2016-11