



CYTOMARK

TransFix[®]

Cellular Antigen Stabilising Reagent

**TransFix/EDTA
Vacuum Blood
Collection Tubes**

Instructions for Use





Product Description

TransFix® is a patented stabilisation solution that prevents cellular degradation in whole blood for analytical testing purposes.

TransFix/EDTA Vacuum Blood Collection Tubes consist of purple capped tubes containing a solution of TransFix and K3EDTA at the correct volume to simultaneously stabilise and anti-coagulate whole blood at the time of collection. TransFix/EDTA is administered at a ratio of 1 part TransFix/EDTA to 5 parts whole blood (1:5). TransFix/EDTA Vacuum Blood Collection Tubes are available in two sizes: a 3ml and 10ml final draw volume tube. TransFix/EDTA Vacuum Blood Collection Tubes are sterilised by gamma radiation. TransFix/EDTA Vacuum Blood Collection Tubes are manufactured by Vacutest KIMA s.r.l, 35020 Arzergrande (PD) Italy.

Principle and Intended Use of TransFix/EDTA Vacuum Blood Collection Tubes

The active components of TransFix stabilise leukocytes and leukocytic antigens for up to 10 days. Ordinarily, blood samples require analysing within 24-48 hours of venepuncture as the immunophenotypic profile is detrimentally affected by natural degradation. Blood samples treated with TransFix will be preserved for up to 10 days, providing the following advantages:

- More time in which to conduct testing – greater flexibility in the laboratory.
- Time for samples to be transported to/from remote sites.
- Reduction in the requirements of repeat sampling.
- The ability to batch samples for testing.

Blood samples taken directly into TransFix/EDTA Vacuum Blood Collection Tubes will be immediately stabilised using the patented TransFix solution, ready for flow cytometric testing, immune monitoring and immunohaematology screening purposes.

Procedure

1. Attach the TransFix/EDTA Vacuum Blood Collection Tube to the plastic needle holder and needle (not supplied with product). Perform phlebotomy. Blood will be aspirated up to the correct total volume and no further.
N.B. Blood should be aspirated fully to avoid an incorrect TransFix/EDTA to blood ratio that could affect results. TransFix/EDTA Vacuum Blood Collection Tubes are compatible with shielded needle devices from most major manufacturers†.
2. Remove the TransFix/EDTA Vacuum Blood Collection Tube from the needle holder and gently invert 10 times to distribute the TransFix/EDTA throughout the blood sample. Do not vortex.
3. Store the TransFix/EDTA Vacuum Blood Collection Tube at 2-25°C in a rack for up to 10 days*.
4. Before conducting any cellular analytical testing, gently mix the TransFix/EDTA-treated blood as before and incubate at room temperature (18 - 25°C) for 15 minutes if refrigerated.
5. Analyse the preparation using the normal procedure e.g. flow cytometric analysis.
N.B. The dilution factor must be accounted for when calculating absolute cell counts i.e. multiply the cell count by 1.2. Cross linking of proteins may occur when using TransFix/EDTA. We therefore recommend that all antibody conjugates are validated in association with TransFix/EDTA prior to routine use. Samples of TransFix/EDTA Vacuum Blood Collection Tubes are available on request.

† Needles (Cat No. 1526502/4/6, 15201, 15213, 15225) and needle holders (Cat No. 169018) can be obtained from Vacutest Kima www.vacutestkima.it.

* Studies have demonstrated that it is possible to analyse TransFix stabilised blood cells that have been stored at temperatures of up to 37°C after 4 days (refer to references), but these conditions are not validated at Cytomark.

Ordering Information

Product Code	Product	Quantity
TVT-03-2	TransFix/EDTA Vacuum Blood Collection Tubes (2 x 3ml tubes)	2 tubes
TVT-03-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 3ml tubes)	50 tubes
TVT-03-100	TransFix/EDTA Vacuum Blood Collection Tubes (100 x 3ml tubes)	100 tubes
TVT-03-200	TransFix/EDTA Vacuum Blood Collection Tubes (200 x 3ml tubes)	200 tubes
TVT-10-2	TransFix/EDTA Vacuum Blood Collection Tubes (2x 10ml tubes)	2 tubes
TVT-10-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 10ml tubes)	50 tubes
TVT-10-100	TransFix/EDTA Vacuum Blood Collection Tubes (100 x 10ml tubes)	100 tubes
TVT-10-200	TransFix/EDTA Vacuum Blood Collection Tubes (200 x 10ml tubes)	200 tubes

Storage Conditions and Stability

TransFix/EDTA Vacuum Blood Collection Tubes are supplied in a sealed foil pouch. Tubes in an unopened pouch are stable at 2 - 25°C for 18 months from date of manufacture or until the expiration date on the label. TransFix/EDTA Vacuum Blood Collection Tubes from opened packages must be stored at 2-8°C and have a shelf life of 6 months from the date that the pouch is opened. **Do not freeze TransFix/Vacuum Blood Collection Tubes at any stage.** A certificate of analysis and a certificate of conformity can be provided with every TransFix/EDTA Vacuum Blood Collection Tube product.

References

Barbara Canonico *et al*, Clinical Cytometry, Vol. 78, 2010, 267-278

Flow Cytometric Profiles, Biomolecular and Morphological Aspects of Transfixed Leukocytes and Red Cells
M. Bergeron *et al*, Clinical Cytometry, Vol. 50, 2002, 86-91

Evaluation of stabilised blood cell products as candidate preparations for quality assessment programs for CD4 T-cell counting

Warning Statements

1. Only use TransFix/EDTA Vacuum Blood Collection Tubes to collect whole blood specimens.
2. Do not use TransFix/EDTA Vacuum Blood Collection Tubes beyond the expiration date on the tubes and packaging.
3. Incubation times or temperatures other than those specified may give erroneous results.
4. TransFix/EDTA is a clear green liquid. Do not use the TransFix/EDTA Vacuum Blood Collection Tubes if there is a change in the physical appearance of the liquid as this may indicate deterioration and will affect test results.
5. TransFix/EDTA treated blood and all materials coming into contact with it should be handled as if capable of transferring infection and disposed of with the proper precautions.
6. Avoid contact of TransFix/EDTA and TransFix/EDTA treated blood samples with the skin and mucous membranes. Any contact should be washed off with cold water immediately.
7. TransFix/EDTA does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.








Cytomark is a division of Caltag Medsystems Ltd, a company registered in the UK, company number 4162330.

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Language	US	GB	D	F	ES	PT	I	GR	PL	CZ
IVD	In-vitro diagnostic	In-vitro diagnostic	In-vitro-Diagnostik	Diagnostic in vitro	Diagnóstico in vitro	Diagnóstico in vitro	La diagnosi in vitro	In-vitro διαγνωστική	In-vitro	In-vitro diagnostická
REF	Code No.	Cat. No.	Kat. Nr.	Reference	No. de. cat.	Referencia	Codice	Κωδικός Αριθμός	Nr katalogowy	Kód
LOT	Lot	Lot	Ch-B	N° de lot	N° lot	N° de lot	Lotto N°	Αριθμός Ποστίδος	Lot	Šarže
	Exp. Date	Exp. Date	Verw. bis	Date of peremption	Caducidad	Validade	Sceadenza	Ημερομηνία Αιτηής	Termin Waznosci	Expirace
	Store	Storage	Lagerung	Stockage	Almacenaje	Armazenar	Conservare	Αποθήκευση	Przechowywanie	Skladování
	Harmful	Harmful	Schädlich	Dangereux	Dañino	Prejudicial	Nocivo	Επικίνδυνο	Szrdodliwy	Zdravi Skodlivy
	Sterilized using irradiation	Sterilised using irradiation	Sterilisation durch Bestrahlung	Stérilisé par irradiation	Esterilizado con radiación	Esterilizado por irradiación	Sterilizzato con radiazioni	Αποστειρώθηκε με χρήση ακτινοβολίας	Steryliżowana promieniowaniem	Sterilizován o ozářením
	Do not reuse	Do not reuse	Nicht wiederverwenden	Ne pas réutiliser	No vuelva a usar	Não reutilize	Non riutilizzare	Μην ξαναχρησιμοποιείτε	Nie używać ponownie	Nepoužívejte opakovaně
	Consult Instructions for use	Consult Instructions for use	Beachten Sie die Gebrauchsanleitung	Suivre les instructions d'utilisation	Consultar las instrucciones de uso	Consulte instruções de utilização	Vedere le istruzioni per l'uso	Συμβουλευτείτε τις οδηγίες χρήσης	Odwolaj się do instrukcji obsługi	Nahlednete do návodu k použití
	Manufacturer	Manufacturer	Hersteller	Fabricant	Fabricante	Fabricante	Fabbicante	Κατασκευαστής	Producent	Výrobce