

INSTRUCTIONS FOR USE

Intended Use

TransFix[®] and TransFix Sample Storage Tubes are intended for stabilisation and storage (in the case of Sample Storage Tubes) of 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.

TransFix is for Research Use Only.

Summary and Principles

Immunophenotyping by flow cytometry provides a rapid and accurate assessment of the frequency and type of leucocytes 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.

Subsets of leucocytes can be distinguished by 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]. The TransFix stabiliser acts by preserving the cell surface antigens of lymphocyte subsets until processing and analysis can be performed.

TransFix is available in bulk format: supplied in 1ml and 20ml aliquots in polypropylene vials, or as a 'sample storage tube': consisting of a 1.2ml polypropylene vial containing 0.2ml TransFix.

Reagents

TransFix is a clear green liquid containing formaldehyde and other chemicals.

Disposal

TransFix (EU Waste Code 18-01-06) contains formaldehyde which should be disposed of in accordance with local regulations. Avoid disposing into drainage systems and the environment.

Once the TransFix 'sample storage tube' contains a biological sample it must be considered an 'Absolute Hazard' (EU Waste Code 18-01-03) and disposal is in accordance with local regulations regarding clinical waste.

Precautions and Warnings

1. TransFix is intended for use as specified in this document. It is a Research Use Only reagent for professional use only.
2. Anti-coagulated blood must be kept at room temperature prior to treatment with TransFix.
3. Incubation times or temperatures other than those specified will lead to erroneous results.
4. Treat the sample with TransFix as quickly as possible to ensure the best results and no later than 6 hours after collection.
5. Do not use TransFix after the expiration date on the tubes and packaging.
6. Do not dilute or add other components to TransFix.
7. Do not use cell viability stains on samples treated with TransFix as they are fixed instantaneously.
8. Do not re-use TransFix Sample Storage Tubes.
9. TransFix treated samples and all materials coming into contact with it should be handled as if capable of transmitting infection.
10. Avoid contact of TransFix treated 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.
11. TransFix does not contain any antimicrobial reagents. Microbial contamination should be avoided, or erroneous results may occur.
12. SDS can be obtained at www.cytomark.co.uk or by calling +44(0)1280 827460.

Indications of Product Deterioration

1. Cloudiness or precipitate visible in the TransFix.
2. Colour 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 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. TransFix products are supplied in sealed foil pouches.

Unused **TransFix Sample Storage Tubes** are stable at 2 - 25°C for up to 12 months or until the expiration date on the label. *N.B.* 2 - 8°C storage is advisable where possible.

Unused **TransFix bulk** is stable at 2 - 25°C for up to 24 months or until the expiration date on the label. *N.B.* 2 - 8°C storage is advisable where possible.

Instructions for Use

1. Collect blood by venepuncture into an EDTA vacuum tube according to normal phlebotomy practise.
2. For **TransFix Sample Storage Tubes**, mix the blood sample, remove 1ml and add to the tube.

3. For **Bulk TransFix**, carefully remove the blood collection tube cap and measure the volume of anti-coagulated whole blood within the vacuum tube. Pipette into the blood collection tube the appropriate volume of TransFix at the ratio of 0.2ml TransFix per 1ml of blood.
4. Replace the cap on the blood collection tube, ensuring that there is no leakage.
5. Mix the treated sample carefully. Do not vortex.
6. Store / transport the TransFix treated blood for up to 14 days at 2 - 8°C, **or**, Store / transport the TransFix treated blood at 18-25°C for up to 3 days, and at 2-8°C for a up to a further 4 days.
7. Incubate the treated sample at room temperature (18-25°C) for 15 minutes before use.
8. Re-suspend the cells thoroughly by **gently inverting the tube at least 10 times**. Heavier cells and blood components will sediment over time, forming two distinct layers; this is normal.
9. **Take care when opening blood collection tubes as there may be a build-up of blood in the caps.**
10. Perform analysis by flow cytometry in accordance with the manufacturer's instructions. A 'stain, lyse-no wash' sample preparation method is recommended. Analyse the treated sample within 6 hours before being returned to 2 - 8°C storage for future use, if necessary.
11. **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 stabilised by TransFix may differ from those of untreated cells.
2. Studies have shown that increased levels of haemolysis, icterus and lipemia do not affect the results.

TransFix is quality tested using a panel of markers including CD3, CD4, CD8 and CD45. A certificate of analysis and a certificate of conformity can be provided with every batch of TransFix 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 Description	Catalogue Numbers
TransFix Bulk (1 x 1ml tube)	TFB-01-1-RUO
TransFix Bulk (10 x 1ml tube)	TFB-01-10-RUO
TransFix Bulk (50 x 1ml tube)	TFB-01-50-RUO
TransFix Bulk (1 x 20ml tube)	TFB-20-1-RUO
TransFix Sample Storage Tube (2 x 1.2ml tube)	TF-01-2-RUO
TransFix Sample Storage Tube (10 x 1.2ml tube)	TF-01-10-RUO
TransFix Sample Storage Tube (25 x 1.2ml tube)	TF-01-25-RUO
TransFix Sample Storage Tube (50 x 1.2ml tube)	TF-01-50-RUO

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IFU TransFix RUO
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