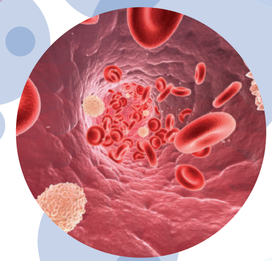
TransFix®

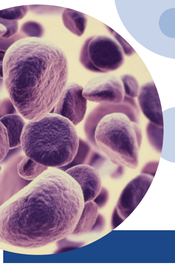
A Cellular Antigen Stabilisation Reagent

TransFix® is a stabilisation reagent that preserves cellular antigens and prevents cellular degradation in a variety of specimen types for flow cytometric analysis.

These specimens include:

- Whole Blood
- Cerebral Spinal Fluid (CSF)
- Circulating Tumour Cells
- Bone Marrow
- Lymph Node Biopsies
- Animal Blood





Why Stabilise Samples?

The quality of biological samples degrades rapidly ex vivo, putting time constraints on flow cytometric analysis. Once cells are taken from the body, they undergo apoptosis and enzymatic degradation which diminishes cell numbers and distorts the true immunophenotype of the specimen. Over time, cell subpopulations in aged samples become indistinguishable, rendering the sample unsuitable for testing.

Benefits of TransFix®

- **Reduced cost:**
  - Greater efficiency in testing – allows for batching of samples prior to testing.
  - Prevent the need for repeat phlebotomy due to degraded samples.
  - Further tests can be performed on the same sample after the initial analysis, without patient recall.
- **Reduced variability:**
  - Ensures sample integrity during transportation between clinical sites.
  - Reduction in pre-analysis variability – all samples preserved at the same time point.
- **Convenience:**
  - Easy to use - just add TransFix and mix by inversion.
  - Eliminates the need for weekend and evening work.
  - Reduces the impact of unexpected machine breakdown or staff shortages.
  - Transport samples at ambient temperature.

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Applications

Whole Blood Stabilisation – CE/IVD

Subsets of leukocytes are distinguished on the basis of their light scatter profile and cell surface antigens by flow cytometry. Quantitative changes in these subsets enable differential diagnosis and monitoring of haematological malignancies (e.g. leukaemia) and immune monitoring of HIV/AIDS patients.

Without stabilisation, flow cytometric analysis of blood samples must be performed within 48 hours of venepuncture. Aged blood samples exhibit indistinguishable cell subsets and inaccurate absolute cell counts, which can lead to erroneous clinical results [1]. These samples are often no longer suitable for flow cytometric examination.

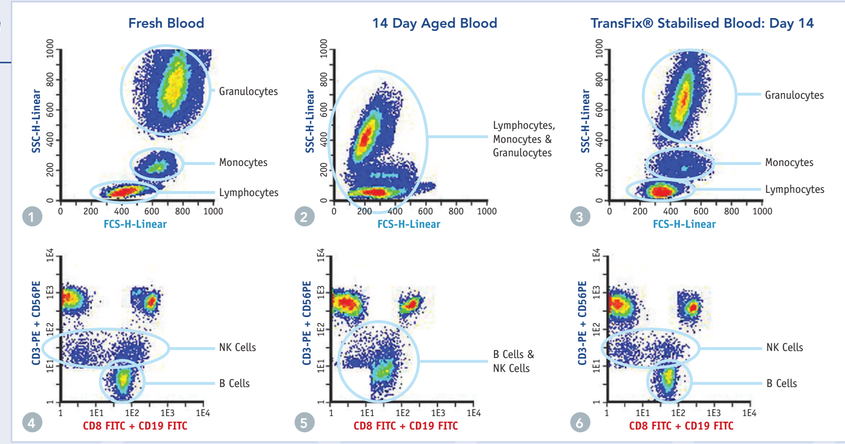
Stabilise whole blood with TransFix/EDTA Vacuum Blood Collection Tubes.

We Recommend...

For best results, samples should be added to TransFix immediately using a 1:5 ratio of TransFix to whole blood, or collected in a TransFix/EDTA Vacuum Blood Collection Tube.

For best results, store at 2-8°C.

Figure 1
Immunophenotypic profile of fresh blood



TransFix has been CE/IVD approved for the stabilisation of human whole blood

TransFix prevents cellular degradation of human whole blood for up to 14 days at 2-8°C, and for up to 4 days at ambient temperature (18-25°C), maintaining the immunophenotypic profile of fresh blood (figure 1) [2]. **This provides the following advantages:**

Clinical Diagnosis and Monitoring

Advantages for Immunophenotyping and HIV/AIDS immune monitoring:

- CE marked for IVD use in Europe.
- Fewer patient recalls due to unusable sample.
- Further tests can be performed on the same sample after the initial analysis, without patient recall.
- Ship samples to centralised reference laboratories without requiring cold chain transportation.
- Batch samples for reduced pre-analysis variability.

Clinical Trials

Advantages of stabilising blood for immunophenotyping in clinical trials:

- Ensures sample integrity during transportation between clinical sites.
- Standardisation of samples across multiple sites (all samples preserved at the same time point, all analysis can be performed at the same site).
- Batched samples for high-throughput analysis, reduced variability, and cost saving.
- Reduction in costs by removing the requirement for cold chain transport.
- Single tube pack sizes and phlebotomy packs available

Cerebrospinal Fluid Stabilisation – RUO

Leukemic infiltration of the Central Nervous System (CNS) is a sign that leucocytes have spread to the brain and spinal cord, and provides poor prognosis in diseases such as childhood acute lymphocytic leukaemia.

Flow cytometry is proving to be useful in detecting malignant cell populations in cerebrospinal fluid (CSF), however low cell counts and rapid decline of cells after lumbar puncture can pose technical challenges for flow cytometric analysis [3] [4].

TransFix has been used for the stabilisation of malignant haematological cells found in CSF.

TransFix/EDTA CSF Sample Storage Tubes have been specifically optimised in collaboration with leading oncologist for CSF stabilisation and have been recommended in guidelines for CSF sample storage, published in the British Journal of Haematology [5].

TransFix has been shown to reduce cellular lysis after 30 minutes compared to fresh CSF and to stabilise key CSF leucocyte markers for up to 72 hours [6]. The stabilisation process preserves light scatter and key antigen expression patterns, including CD10, CD19, CD34, CD45, HLA-DR and CD117.

Stabilise CSF with TransFix/EDTA CSF Sample Storage Tubes

Can TransFix Stabilise Intracellular Markers?

TransFix has been shown to stabilise intracellular markers such as CD79a and MPO for up to 3 days. For intracellular marker analysis a 1 part TransFix to 10 part blood sample ratio is recommended.

Circulating Tumour Cell Stabilisation – RUO

The number of rare circulating tumour cell populations present in patient blood is very low, therefore the usefulness of Circulating Tumour Cell (CTC) assessments depends upon accurate cell counts and the corresponding analysis of molecular targets. The addition of TransFix to blood samples at the time of collection has been shown to significantly extend the integrity of CTC's within the samples. And has facilitated the use of novel filtration and detection systems to analyse CTCs [7] [8].

Stabilise CTCs with Circulating Tumour Cell TransFix/EDTA Vacuum Blood Collection Tubes

Other Applications - RUO

Bone Marrow Stabilisation - TransFix has been shown to stabilise bone marrow samples for enumeration of mast cells and immunophenotyping of BMSCs [9] [10]. This prevents deterioration of cells prior to flow cytometric analysis, and allows researchers to complete time sensitive aspects of studies.

Lymph Node Stabilisation - TransFix has been used to stabilise cellular antigens and increase cell yields within fine needle aspirations and other lymph nodes biopsies. This allows immunophenotyping by flow cytometry to be conducted at a time that is more convenient to the operator.

Animal Blood Stabilisation - The addition of TransFix to animal blood samples at the time of collection has significantly extended the integrity of the samples in several different species, particularly useful in immune monitoring of farming stock such as poultry [11] [12].

Stabilise these sample types with TransFix Sample Storage Tubes or TransFix Reagent

TransFix®

Product Formats

TransFix/EDTA Vacuum Blood Collection Tubes – CE/IVD

Plastic, direct draw collection tubes used to instantaneously stabilise 3 or 9ml of venous blood at the point of collection, providing the optimal stability for whole blood specimens. These tubes fit all international standard safety ports.

Product Code	Description
TVT-03-1	TransFix/EDTA Vacuum Blood Collection Tubes (1 x 3ml tube)
TVT-03-2	TransFix/EDTA Vacuum Blood Collection Tubes (2 x 3ml tubes)
TVT-03-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 3ml tubes)
TVT-03-xxxxx-PP	3ml TransFix Phlebotomy Packs (Avail. choice of 6 sizes of needle)
TVT-09-1	TransFix/EDTA Vacuum Blood Collection Tubes (1x 9ml tube)
TVT-09-2	TransFix/EDTA Vacuum Blood Collection Tubes (2x 9ml tubes)
TVT-09-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 9ml tubes)
TVT-09-xxxxx-PP	9ml TransFix Phlebotomy Packs (Avail. choice of 6 sizes of needle)

TransFix Phlebotomy Packs contain an individually wrapped TransFix/EDTA Vacuum Blood Collection Tube and a safety port with integrated needle.

Circulating Tumour Cell TransFix/EDTA Vacuum Blood Collection Tubes – RUO

Blood collection tubes prefilled with sufficient TransFix for the collection and stabilisation of circulating tumour cells in 9ml of blood.

Product Code	Description
CTC-TVT-09-2	Circulating Tumour Cell TransFix/EDTA Vacuum Blood Collection Tubes (2 x 9ml tubes)
CTC-TVT-09-50	Circulating Tumour Cell TransFix/EDTA Vacuum Blood Collection Tubes (50 x 9ml tubes)

TransFix/EDTA CSF Sample Storage Tubes – RUO

5ml screw cap tubes containing 0.2ml of TransFix/EDTA, optimised to stabilise Cerebrospinal Fluid (CSF).

Product Code	Description
TF-CSF-5-2	TransFix/EDTA CSF Sample Storage Tubes (2 x 5ml tubes)
TF-CSF-5-10	TransFix/EDTA CSF Sample Storage Tubes (10 x 5ml tubes)
TF-CSF-5-25	TransFix/EDTA CSF Sample Storage Tubes (25 x 5ml tubes)
TF-CSF-5-50	TransFix/EDTA CSF Sample Storage Tubes (50 x 5ml tubes)

TransFix Sample Storage Tubes – CE/IVD

1.2ml tubes containing 0.2ml of TransFix. These tubes do not contain an anti-coagulant, giving flexibility to the user to stabilise blood collected with anticoagulant other than EDTA.

Product Code	Description
TF-01-2	TransFix Sample Storage Tubes (2 x 1.2ml tubes)
TF-01-10	TransFix Sample Storage Tubes (10 x 1.2ml tubes)
TF-01-25	TransFix Sample Storage Tubes (25 x 1.2ml tubes)
TF-01-50	TransFix Sample Storage Tubes (50 x 1.2ml tubes)

TransFix Reagent – CE/IVD

TransFix reagent in 1 and 20ml aliquot sizes and in pack sizes of 2, 10 and 50 x 1ml tubes. This gives the end user most flexibility with regard to application of TransFix to research samples.

Product Code	Description
TFB-01-1	1ml TransFix
TFB-01-10	10 x 1ml TransFix

Product Code	Description
TFB-01-50	50 x 1ml TransFix
TFB-20-1	20ml TransFix

Further information, protocols, certificates of analysis, and our bibliography, visit www.cytomark.co.uk

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Contact Details

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Or email:

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Further information, protocols, certificates of analysis, and our bibliography can be found at:

www.cytomark.co.uk

How to Order

Contact your local distributor:

International Customers

We have a network of international distributors. Please visit:
http://www.cytomark.co.uk/distributors.php
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UK Customers

Customers in the UK can order from Caltag Medsystems:
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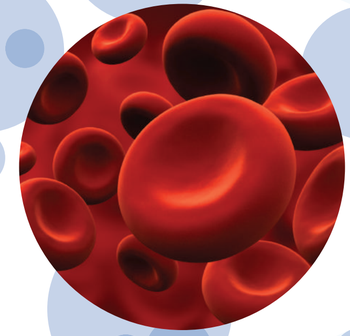
TransFix®

Preserves Cells and Cellular Antigens for up to 14 Days prior to Analysis by Flow Cytometry



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Dedicated to the development of cell stabilisation reagents