

## PRODUCT INFORMATION SHEET

### 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.

### Precautions and Warnings

- TransFix is intended for use as specified in this document. It is a Research Use Only reagent for professional use only.
- TransFix and TransFix Sample Storage Tubes are only for use with flow cytometry analysis.
- Anti-coagulated blood must be kept at room temperature prior to treatment with TransFix.
- Incubation times or temperatures other than those specified will lead to erroneous results.
- Do not use TransFix after the expiration date on the tubes and packaging.
- Do not dilute or add other components to TransFix.
- Do not use cell viability stains on samples treated with TransFix as they are fixed instantaneously.
- TransFix Sample Storage Tubes are single-use only. Do not re-use.
- Ensure the correct sample to TransFix ratio is used as per instructions; an incorrect blood-to-additive ratio and may lead to poor product performance and incorrect analytic results.
- TransFix treated samples and all materials coming into contact with it should be handled as if capable of transmitting infection.

### Reagents

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

### GHS Hazard Classification

TransFix

#### WARNING



Safety Data Sheet can be obtained at  
[www.caltag.co.uk](http://www.caltag.co.uk)

#### Formaldehyde

H317 - May cause an allergic skin reaction.  
H350 - May cause cancer.  
P261 - Avoid breathing fume, mist, spray, vapours.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### Indications of Product Deterioration

- Cloudiness or precipitate visible in the TransFix.
- Colour change of TransFix from a clear green liquid.
- TransFix change from liquid to solid.

If indications of product deterioration occur, do not use and contact Caltag immediately on: +44(0)1280 827460 or [support@caltag.co.uk](mailto:support@caltag.co.uk).

### Pre-Use Storage Conditions and Stability

TransFix products are supplied in sealed foil pouches and shipped at ambient conditions. Additional insulation may be required for shipment during temperature conditions of below -5°C.

Unused **TransFix Sample Storage Tubes** are stable at 2 - 25°C for up to 12 months or until the expiration date on the label. 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.

### Materials needed but not supplied

- Blood collection tubes and materials for sampling.
- Automatic pipettes with disposable tips for 10, 20, 100 and 1,000 µL.
- Flow cytometry tubes
- Flow cytometry calibration and control reagents
- Specific fluorescent antibodies and isotype controls
- Red blood cell lysing solution
- Automatic agitator/vortex machine
- Flow cytometer

### Instructions for Use

- Collect blood by venepuncture into an EDTA vacuum tube according to normal phlebotomy practise. Treat sample with TransFix within 6 hours of venepuncture:
- For **TransFix Sample Storage Tubes**, mix the blood sample, remove 1ml and add to the tube.
- 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.
- Replace the cap on the sample tube, ensuring that there is no leakage.
- Mix the treated sample carefully. Do not vortex.
- 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. Incubate the treated sample at room temperature (18-25°C) for 15 minutes before use.
- 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.
- Take care when opening **TransFix Sample Storage Tubes** as there may be a build-up of blood in the caps.
- Stain and analyse your stabilised blood sample as per your usual flow cytometry protocol (N.B. see Notes).

### Notes:

- It is recommended that all antibody conjugates are validated in association with TransFix prior to use.
- Use caution when implementing automatic gating strategies as light scatter positions of cells stabilised by TransFix may differ from those of untreated cells.
- Gating for lymphocytes should be performed on CD45+SSc.
- If calculating absolute cell counts, the dilution with TransFix must be accounted for. I.e., adjust the absolute cell count by multiplying the output by 1.2.

### Disposal

TransFix 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 disposed of in accordance with local regulations regarding clinical waste.

### References

- 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.

### Symbols Glossary

For symbols glossary, please see [www.caltag.co.uk](http://www.caltag.co.uk).

### Ordering Information

Please call Caltag on +44(0)1280 827460 or email [support@caltag.co.uk](mailto:support@caltag.co.uk) for assistance. Additional information can be found online at [www.caltag.co.uk](http://www.caltag.co.uk). A certificate of conformity can be provided with every batch of TransFix products.

| 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 (50 x 1.2ml tube) | TF-01-50-RUO      |



Caltag Medsystems Ltd, Whiteleaf Business Centre, 11 Little  
Balmer, Buckingham, MK18 1TF, UK