

PRODUCT INFORMATION SHEET

Intended Use

TransFix is a solution that preserves cellular antigen expression (cluster of differentiation markers), and cell morphology within biological samples such as: peripheral whole blood and cerebrospinal fluid. Samples treated with TransFix can be maintained for up to 14 days prior to analysis by flow cytometry.

TransFix is a General Purpose Reagent

Summary and Principles

Immunophenotyping by flow cytometry provides a rapid and accurate assessment of the frequency and type of leukocytes in a patient sample. Logistics, such as transport of samples from collection site to analysis location, create situations in which sample analysis cannot be performed immediately after collection. Sample preservation for future analysis provides a solution which addresses such situations.

The TransFix stabilizer acts by preserving the cell surface antigens until processing and analysis can be performed.

Subsets of leukocytes can be distinguished on the basis of cell surface antigens using fluorescent antibodies and flow cytometry. Qualitative and quantitative changes in leukocyte subsets are used to identify and monitor immunodeficiency and hematologic diseases [1, 4, 5].

TransFix is designed to preserve the specimens' qualitative and quantitative leukocyte subset characteristics.

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 or 5ml polypropylene vial containing 0.2ml TransFix.

Reagents

TransFix is a clear green liquid containing paraformaldehyde and other cell preservatives. Refer to the SDS for safety and disposal information.

Precautions and Warnings

1. TransFix is a General Purpose Reagent.
2. For stabilizing peripheral blood samples, anti-coagulated blood must be kept at room temperature prior to treatment. Incubation times or temperatures other than those specified may lead to erroneous results.
3. Do not use TransFix after the expiration date on the tubes and packaging.
4. Do not dilute or add other components to TransFix.
5. Do not use cell viability stains on samples treated with TransFix as they are fixed instantaneously.
6. Do not re-use TransFix Sample Storage Tubes.
7. TransFix treated samples and all materials coming into contact with it should be handled as if capable of transmitting infection.
8. Avoid contact of TransFix treated 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.
9. TransFix does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
10. SDS can be obtained at www.cytomark.com, by calling 01144 1280 827460 or by calling MBL International at 800-200-5459.

Indications of Product Deterioration

1. Cloudiness or precipitate visible in unused TransFix vials.
2. Color change of TransFix from a clear green liquid in unused TransFix vials.
3. Reagent change from liquid to solid in unused TransFix vials.
4. If indications of product deterioration occur, do not use TransFix and contact MBL Bion immediately at: technical@mblintl.com

Storage Conditions and Stability

TransFix Sample Storage Tubes and TransFix bulk products are supplied in a sealed foil pouch.

Unused TransFix Sample Storage Tubes are stable at 2 - 8°C for up to 12 months or until the expiration date on the label. When in use, TransFix Sample Storage Tubes can be removed from refrigerated storage for up to 2 hours at room temperature (18 - 25°C) before being returned to 2 - 8°C storage.

Unused TransFix bulk can be stored at 18-25°C although it is advisable to store it at 2 - 8°C to reduce evaporation. TransFix bulk may be used until the expiration date on the label.

All TransFix products are shipped at ambient temperature (2 - 25°C). Proper insulation may be required for shipment during extreme temperature conditions. Do not freeze TransFix.

Instructions for Use – Peripheral Blood Samples

1. Collect blood by venipuncture into an EDTA vacuum tube according to CLSI document H3-A62 [2].
2. Carefully remove the blood collection tube cap and determine the volume of anti-coagulated whole blood within the vacuum tube.
3. Pipette into the blood collection tube the appropriate volume of TransFix at the ratio of 0.2ml TransFix per 1ml of blood.
Note: Blood samples should be treated with TransFix immediately after collection, but failing this, blood must be less than 6 hours old when it is treated with TransFix. Do not refrigerate the sample before treatment with TransFix.
4. Replace the cap on the blood collection tube, ensuring that there is no leakage and mix gently by inversion at least 10 times. Inadequate or delayed mixing may result in inaccurate test results. Do not

vortex.

5. Store / transport the TransFix treated blood for up to 14 days at 2 - 8°C or for up to 4 days at 18 - 25°C [3].
6. If refrigerated, incubate the treated blood sample at room temperature (18 - 25°C) for 15 minutes prior to use. Then mix the treated blood by rolling the tube between the hands 10 times and by inverting as before.
Note: Heavier cells and blood components will sediment over time, forming two distinct layers. This is normal. Re-suspend the cells thoroughly by repeating step 6 if necessary.
7. Perform analysis by flow cytometry in accordance with the manufacturer's instructions. A 'stain, lyse-no wash' sample preparation method is recommended. Blood stabilized by TransFix should be analyzed within 6 hours before being returned to 2 - 8°C storage for future use, if necessary.

Instructions for Use – Cerebrospinal Fluid Samples

1. Collect at least 1ml cerebrospinal fluid (CSF) by lumbar puncture according to the relevant Clinical Standard.
Note: CSF samples can be collected directly into the 5ml TransFix Sample Storage Tube, up to the 2.5ml graduation mark.
2. If necessary, carefully transfer 1 – 2ml CSF into the 5ml TransFix Sample Storage Tube (up to the 2.5ml graduation mark) using a manual pipette as soon as possible.
Note: CSF samples must be transferred to the 5ml TransFix Sample Storage Tube within 2 hours of lumbar puncture.
3. Use a manual pipette to mix the TransFix-CSF solution and close the cap. Store / transport the 5ml TransFix Sample Storage Tube for up to 72 hours at 2 - 8°C.
4. After storage, open the cap and transfer all of the specimen into a flow cytometry tube (approx. dimensions 0.5" x 3") using a manual pipette.
5. Rinse out the 5ml TransFix Sample Storage Tube with 3ml PBS and transfer to the flow cytometry tube using a manual pipette.
6. Centrifuge the specimen at 540g for 5 minutes, at room temperature, with the brake off.
7. Aspirate the supernatant using a Pasteur pipette without disturbing the cell pellet and discard, leaving approx. 150µl cell suspension.
8. Carefully re-suspend the remaining cell suspension using a manual pipette. Stain the sample with the appropriate fluorochrome conjugated antibodies targeting cell surface antigens, according to the manufacturer's instructions.
9. Incubate for 15 minutes at room temperature, in the dark.
10. Add 3ml PBS to the specimen using a manual pipette, mix and centrifuge at 540g for 5 minutes, at room temperature, with the brake off.
11. Aspirate the supernatant using a Pasteur pipette without disturbing the cell pellet and discard, leaving approx. 150µl cell suspension.
12. Carefully re-suspend the remaining cell suspension with 150µl PBS using a manual pipette.
Note: Prior to CSF acquisition, run distilled water through the flow cell to remove any residual cells.
13. Acquire the specimen on a flow cytometer according to the manufacturer's instructions within 30 minutes of this preparation.

A certificate of analysis can be provided with every batch of TransFix.

Note: It is recommended that all antibody conjugates are validated in association with TransFix prior to use. Samples of TransFix are available on request and a list of antibodies validated by Cytomark can be found on www.cytomark.com.

Note:

- a. Light scatter positions of cells stabilized by TransFix 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 accordingly so that absolute cell counts are automatically corrected for TransFix treated samples.
- c. As is the case with most clinical laboratory specimens, hemolysis, icteris and lipemia may affect the results obtained on blood samples preserved with TransFix. Grossly hemolyzed samples should be rejected.

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.
2. Clinical and Laboratory Standards Institute. H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; 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.
4. Use of TransFix Cerebrospinal Fluid Storage Tubes Prevents Cellular Loss and Enhances Flow Cytometric Detection of Malignant Hematological Cells after 18 Hours of Storage. De Jongste et al, Clinical Cytometry, 2013, 0008:00-00.
5. Guidelines on the use of Multicolour Flow Cytometry in the Diagnosis of Haematological Neoplasms. Johansson et al, British Journal of Haematology, 2014, 165, 455-488.

PRODUCT INFORMATION SHEET

Glossary of Harmonized Symbols

Catalog Number Use by Batch Code

Manufacturer Temperature Limitation Biological Risk

Consult Instructions For Use Do not re-use Irritant

Suspected Carcinogen

Ordering Information

Please call MBL International Sales Department at 800-200-5459 for assistance. Additional information can be found online at www.cytomark.com.

Bulk Format Product Descriptions	Catalog Numbers
1ml TransFix	TF-B1-1
10x 1ml TransFix	TF-B1-10
50x 1ml TransFix	TF-B1-50
20ml TransFix	TF-B20-1
Sample Storage Tube Product Descriptions	Catalog Numbers
TransFix Sample Storage Tubes (2 x 1.2ml tubes)	TF-1-2
TransFix Sample Storage Tubes (2 x 5ml tubes)	TF-5-2
TransFix Sample Storage Tubes (10 x 1.2ml tubes)	TF-1-10
TransFix Sample Storage Tubes (10 x 5ml tubes)	TF-5-10
TransFix Sample Storage Tubes (25 x 1.2ml tubes)	TF-1-25
TransFix Sample Storage Tubes (25 x 5ml tubes)	TF-5-25
TransFix Sample Storage Tubes (50 x 1.2ml tubes)	TF-1-50
TransFix Sample Storage Tubes (50 x 5ml tubes)	TF-5-50

Distributed by:



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Caltag Medsystems Ltd, Buckingham, MK18 1TF, UK