TransFix® Cellular Antigen Stabilising Reagent

CE

CYTOMARK

INSTRUCTIONS FOR USE

Intended Use

TransFix is a solution intended for stabilising human 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 stabilisation.

TransFix is an *in-vitro* diagnostic medical device.

Summary and Principles

Immunophenotyping by flow cytometry provides a rapid and accurate assessment of the frequency and type of leucocytes in a patient sample. However, when blood is collected in routine EDTA tubes, any delay in testing, such as transport of samples from 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.

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

Subsets of leucocytes can be distinguished on the basis of 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].

TransFix is designed to preserve the specimens' qualitative and quantitative leucocyte subset characteristics. It 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 paraformaldehyde and other cell preservatives. Refer to the SDS for safety and disposal information.

Precautions and Warnings

1. TransFix is intended for use as specified in this document. It is an *in-vitro* diagnostic medical device.
2. Anti-coagulated blood must be kept at room temperature prior to treatment. Incubation times or temperatures other than those specified will 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. To reduce build-up of blood in the caps of TransFix Sample Storage Tubes after use, briefly spin the tubes before opening.
8. TransFix treated samples and all materials coming into contact with it should be handled as if capable of transmitting infection.
9. 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.
10. TransFix does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
11. 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 unused TransFix vials.
2. Colour 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 Caltag Medsystems immediately on: +44(0)1280 827460 or cytomark@caltagmedsystems.co.uk.

Storage Conditions and Stability

TransFix Sample Storage Tubes and 1ml TransFix bulk products are supplied in a sealed foil pouch. 20ml TransFix bulk is supplied in a cardboard box with a foam insert.

Unused TransFix is stable at 2 - 25°C for up to 24 months or until the expiration date on the label. 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 and TransFix Sample Storage Tubes can be stored at 18-25°C although 2 - 8°C storage is advisable to reduce evaporation.

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

Instructions for Use – Peripheral Blood Samples

1. Collect blood by venepuncture 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. For TransFix Sample Storage Tubes, add 1ml blood to the tube.
   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. External studies have shown that TransFix can successfully stabilise blood samples at 37°C for up to 7 days [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. **Take care when opening blood collection tubes and briefly spin TransFix Sample Storage Tubes to reduce the build-up of blood in the caps.**
   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 stabilised by TransFix should be analysed within 6 hours before being returned to 2 - 8°C storage for future use, if necessary.

Note:

a. Light scatter positions of cells stabilised 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 by 1.2 so that absolute cell counts are automatically corrected for TransFix treated blood samples.
c. Studies have shown that moderately high levels of haemolysis, icterus and lipemia do not affect the results. Grossly haemolysed samples should be rejected.

A certificate of analysis and a certificate of conformity 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.co.uk.

References

1. Evaluation of stabilised 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 Venepuncture; 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.

Ordering Information

Please call Cytomark on +44(0)1280 827460 for assistance. Additional information can be found online at www.cytomark.co.uk.

Glossary of Harmonised Symbols

Catalogue No.


Use by

Batch Code


Manufacturer


Temperature Limitation

In-vitro Diagnostic Medical Device


Consult Instructions For Use


Do not re-use


Biological Risk


Irritant


Suspected Carcinogen

CE

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