

PRODUCT INFORMATION SHEET

Intended Use

TransFix[®] Cerebrospinal Fluid (CSF) Sample Storage Tubes are intended for the stabilisation and storage of human CSF specimens for characterisation of infiltrated white blood cells by flow cytometry. Recovery of infiltrated leucocyte subsets can be accomplished over a 3-day period following stabilisation.

TransFix CSF Sample Storage Tubes are **'Research Use Only'** products.

Summary and Principles

Within CSF specimens, the qualitative and quantitative characterisation of infiltrated leucocytes via flow cytometry is an important tool for identification of various immunodeficiencies and haematologic diseases [1-4]. However, the number of leucocytes present in CSF is often very low and degrade quickly. Therefore, assessment of these cells is reliant upon urgent analysis which is not always possible.

Subsets of leucocytes can be distinguished by cell surface antigens using fluorescent antibodies and flow cytometry. The TransFix stabiliser acts by preserving cell surface antigens of lymphocyte subsets until processing and analysis can be performed.

Addition of CSF to TransFix CSF Sample Storage Tubes at the time of lumbar puncture has been shown to significantly extend the integrity of these leucocytes compared to unstabilised samples or stabilisation by other methods [1, see Representative Data Figure 1]. TransFix preserves the cell surface antigens until processing and analysis can be performed [1, 2].

TransFix CSF 1-4 mL Sample Storage Tubes consist of 5 mL polypropylene vials containing 0.2 mL TransFix suitable for stabilising 1-4 mL of CSF.

TransFix CSF 0.25-1 mL Sample Storage Tubes consist of 2 mL polypropylene vials containing 0.05 mL TransFix suitable for stabilising 0.25-1 mL of CSF.

Precautions and Warnings

1. TransFix CSF Sample Storage Tube is intended for use as specified in this document. It is an 'In Vitro Diagnostic' product for professional use only.
2. TransFix CSF Sample Storage Tubes are only for use with flow cytometry analysis.
3. TransFix CSF Sample Storage Tubes must be stored at 2-8°C. Do not freeze.
4. Do not use after the expiration date on the tubes and packaging.
5. Do not dilute or add other components to the tube before use.
6. Do not use cell viability stains on samples treated with TransFix as they are fixed instantaneously.
7. TransFix CSF Sample Storage Tubes are single-use only. Do not re-use.
8. Ensure the correct sample volume is used as per instructions; an incorrect sample-to-additive ratio may lead to poor product performance and incorrect analytic results.

9. TransFix treated samples and all materials coming into contact with it should be handled as if capable of transmitting infection.

Reagents

TransFix CSF Sample Storage Tubes contain EDTA and TransFix, a clear green liquid containing formaldehyde and other chemicals.

GHS Hazard Classification

TransFix



GHS07 GHS08

Safety Data Sheet can be obtained at www.cytomark.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

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.

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

Pre-Use Storage Conditions and Stability

TransFix CSF Sample Storage Tubes are shipped in ambient conditions, between temperatures of -5°C to 26°C. Additional insulation may be required for shipment during extreme temperature conditions. **TransFix CSF Sample Storage Tubes must be stored at 2-8°C on arrival.**

Unused TransFix CSF Sample Storage Tubes are stable at 2-8°C for up to 12 months or until the expiration date on the label.

TransFix CSF Sample Storage Tubes are supplied in sealed foil pouches.

Materials needed but not supplied

- Sample 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
- Automatic agitator/vortex machine
- Flow cytometer

Instructions for Use

1. Collect cerebrospinal fluid (CSF) by lumbar puncture according to the relevant clinical standard.
2. **TransFix 1-4 mL CSF Tubes:** Carefully mix the sample and transfer 1-4 mL CSF into the 5 mL tube using a manual pipette as soon as possible and no later than 1 hour after lumbar puncture.
3. **TransFix 0.25-1 mL CSF Tubes:** Carefully mix the sample and transfer 0.25-1 mL CSF into the 2 mL tube using a manual pipette as soon as possible and no later than 1 hour after lumbar puncture.
4. Gently mix the TransFix treated sample and close the cap.
5. Store / transport the TransFix treated sample for up to 72 hours at 2-8°C.
6. Stain and analyse your stabilised CSF sample as per your usual CSF flow cytometry protocol (N.B. see Notes).

Notes

1. It is recommended that all antibody conjugates are validated in association with TransFix CSF Sample Storage Tubes prior to use.
2. Use caution when implementing automatic gating strategies as light scatter positions of cells stabilised by TransFix may differ from those of untreated cells.
3. Gating for lymphocytes should be performed on CD45+/SSc.
4. If calculating absolute cell counts, the dilution with TransFix must be accounted for. I.e., for a sample size of 1 mL adjust the absolute cell count by multiplying the output by 1.2. For a sample size of 2 mL adjust the absolute cell count by multiplying the output by 1.1, etc.

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 CSF Sample Storage Tube contains a biological sample it must be disposed of in accordance with local regulations regarding clinical waste.

References

1. Use of TransFix Cerebrospinal Fluid Storage Tubes Prevents Cellular Loss and Enhances Flow Cytometric Detection of Malignant Haematological Cells after 18 Hours of Storage. De Jongste *et. al.*, Cytometry Part B 2014; 86B: 272– 279.
2. 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.
3. Flow Cytometric Characterization of Cerebrospinal Fluid Cells. De Graaf MT *et. al.*, Cytometry, 2011, 80B: 271-281.
4. ESCCA/ISCCA Protocol for the Analysis of Cerebrospinal Fluid by Multiparametric Flow-cytometry in Hematological Malignancies. Del Principe *et. al.*, Cytometry, 2020; 1– 13.

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. A certificate of conformity can be provided with every batch of TransFix CSF Sample Storage Tubes.

Product Description	Catalogue Numbers
TransFix CSF 0.25-1 mL Sample Storage Tube (2 tubes)	TF-CSF-S-2-RUO
TransFix CSF 0.25-1 mL Sample Storage Tube (10 tubes)	TF-CSF-S-10-RUO
TransFix CSF 0.25-1 mL Sample Storage Tube (50 tubes)	TF-CSF-S-50-RUO
TransFix CSF 1-4 mL Sample Storage Tube (2 tubes)	TF-CSF-L-2-RUO
TransFix CSF 1-4 mL Sample Storage Tube (10 tubes)	TF-CSF-L-10-RUO
TransFix CSF 1-4 mL Sample Storage Tube (50 tubes)	TF-CSF-L-50-RUO

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Revision 8, 2024-11