Circulating Tumor Cell TransFix/EDTA Vacuum Blood Collection Tubes

Product Information Sheet

Application
Circulating Tumor Cell TransFix/EDTA Vacuum Blood Collection Tubes (CTC-TVTs) are intended for collection and storage of human whole blood specimens for CTC evaluation. This product is for Research Use Only (RUO).

Summary and Principles
Circulating tumor cells (CTCs) are cells from the primary tumor which have invaded and moved through the walls of nearby blood vessels and circulate in the blood stream. These circulating tumor cells can invade the walls of the capillaries at a distant location and migrate into the surrounding tissue which can result in the formation and growth of secondary tumors; a process called metastasis.

The number of rare circulating tumor cell populations present in human blood is very low, therefore the usefulness of CTC assessments depends upon accurate cell counts and the corresponding analysis of molecular targets. Addition of Transfix to blood samples at the time of collection has been shown to significantly extend the integrity of CTCs within the samples [1, 2].

CTC-TVTs consist of purple capped polyethylene terephthalate tubes that are designed for direct-draw blood collection. They contain a solution of Transfix and K$_2$EDTA at the correct volume to simultaneously stabilize and anti-coagulate whole blood at the time of collection. The stabilizer acts by preserving CTCs until processing and analysis can be performed.

CTC-TVTs are a 9ml final draw volume tube. The vacuum contained within the tube ensures that the Transfix/EDTA reagent is administered at the correct ratio of 1 part Transfix/EDTA to 19 parts whole blood. CTC-TVTs are sterilized by gamma radiation.

Reagents
TVTs contain the anti-coagulant, K$_2$EDTA, and the Transfix cell preservative in a liquid medium.

Precautions and Warnings
1. This product is for Research Use Only.
2. Do not freeze the CTC-TVts, or blood specimens collected in CTC-TVts. Incubation times or temperatures other than those specified may lead to erroneous results.
3. Do not use CTC-TVts after the expiration date on the tubes and packaging.
4. Only use CTC-TVts to collect human whole blood specimens. Do not use tubes for collection of materials to be injected into patients.
5. Do not dilute or add other components to CTC-TVts.
6. Under-filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
7. CTC-TVts should only be used by trained phlebotomists.
8. Do not transfer specimens that have been collected in other tubes or specimens treated with other preservatives / anti-coagulants into CTC-TVts.
9. Do not use cell viability stains on blood collected in CTC-TVts as they are fixed instantaneously.
10. Do not re-use CTC-TVts.
11. Transfix/EDTA treated blood and all materials coming into contact with it should be handled as if capable of transmitting infection.
12. Avoid contact of Transfix/EDTA and Transfix/EDTA treated blood 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.
13. Product should be disposed with infectious medical waste.
14. Remove and reinsert the cap by grasping with a simultaneous twisting and pulling action, not by a thumb roll method.
15. Transfix/EDTA does not contain any antimicrobial reagents. Microbial contamination should be avoided or erroneous results may occur.
16. SDS can be obtained at www.cytomark.com, by calling 01144 1280 827460 or by calling MBL International at 800-200-5459.

Prevention of Backflow
Since CTC-TVts contain chemical additives, it is important to avoid possible backflow from the tube. To guard against backflow:

1. Keep subject’s arm in the downward position during the collection procedure.
2. Hold the tube with the cap in the uppermost position so that the tube contents do not touch the stopper in the cap or the end of the needle during sample collection.
3. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
4. Tube contents should not touch stopper in cap or the end of the needle during collection.

Product Appearance
1. Please note that the stabilization solution within these tubes may change color from green to grey/blue color. This does not affect its functional performance.

Storage Conditions and Stability
CTC-TVts are supplied in a sealed foil pouch that contains a humified environment in order to minimize Transfix/EDTA evaporation from the tubes. Tubes in an unopened pouch are stable at 2 - 8°C until the expiration date on the label. Once the pouch is opened, CTC-TVts have a shelf life of 6 months from the date that the pouch is opened, or until the expiration date on the label. CTC-TVts removed from an opened pouch must be used within 2 hours at room temperature (18 - 25°C), otherwise returned to 2 - 8°C storage. Do not freeze CTC-TVts.

Instructions for Use
1. Collect blood by venipuncture according to CSLI document H3-A62 [2]. CTC-TVts are compatible with shielded needle devices from most major manufacturers.
2. Fill tube completely. Blood will be aspirated up to the correct total volume and no further. This is important to avoid an incorrect Transfix/EDTA to blood ratio that could affect results.
3. Remove the CTC-TVT from the needle holder and immediately mix by gentle inversion 10 times to distribute the Transfix/EDTA throughout the blood sample. Inadequate or delayed mixing may result in inaccurate test results. Do not vortex.
4. After collection, store/transport the blood filled CTC-TVts at room temperature 18 - 25°C for up to 5 days.

Note: Heavier cells and blood components will sediment over the 5 day storage period, forming two distinct layers. This is normal. Re-suspend the cells thoroughly by gentle inversion 10 times if necessary.

5. Identify and enumerate CTCs by preferred method such as flow cytometry.

A certificate of analysis can be provided for each CTC-TVt batch.

References
1. Assessment of circulating tumor cells with a novel, filtration-based method, in a phase IIIb multicenter study for postmenopausal, HER2- negative, estrogen receptor-positive, advanced breast cancer patients. Faching et al., ASCO Meeting Abstracts Jun 17, 2013:591

Glossary of Harmonized Symbols

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<th>REF</th>
<th>Catalog Number</th>
<th>Use by</th>
<th>LOT</th>
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<td>Manufacturer</td>
<td>Temperature Limitation</td>
<td>RUO</td>
<td>Research Use Only</td>
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<tr>
<td>Consult Instructions For Use</td>
<td>Do not re-use</td>
<td>Biological Risk</td>
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<tr>
<td>Irritant</td>
<td>Suspected Carcinogen</td>
<td>STERILE</td>
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Ordering Information
Please call MBL International Sales Department at 800-200-5459 for assistance. Additional information can be found online at www.cytomark.com.

Circulating Tumor Cells

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<th>CTC-TVt Product Descriptions</th>
<th>Catalog Numbers</th>
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<td>CTC-TVt-09-2</td>
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