ENGLISH

CapiJect® Capillary Blood Collection Tubes

CE

FOR IN VITRO DIAGNOSTIC USE

IVD

Non-Sterile

November 2004

Intended Use: CapiJect® Capillary Blood Collection tubes are used to collect, transport and store blood specimens collected by skin puncture.

Product Description: The CapiJect® Capillary Blood Collection tube is comprised of plastic collection tube and a color-coded plastic cap for easy tube identification. The collection tubes contain an integral collector for facilitating blood flow into tube. The cap is replaced over the collector after blood collection. Each tube contains a color- coded fill line, lot number and expiration date.

SERUM TUBES
The interior surface of the serum tubes is coated with silicone to facilitate blood flow into the tube and to minimize adherence of red cells to the tube walls.

PLASMA TUBES
Plasma tubes contain an anticoagulant which prevents clotting of the blood. Plasma tubes containing gel can be centrifuged to allow gel barrier formation and analysis of the plasma. Non-gel tubes containing anticoagulant may be continually mixed prior to sampling for whole blood analysis as appropriate for the desired test.

TUBES CONTAINING GEL
The gel contained in select CapiJect® tubes is intended to provide a cell barrier which is formed as a result of the centrifugation process. Gel-filled serum tubes also contain a coating of silica particles that will enhance clot activation upon gentle inversion of the tube.

AMBER-COLORED TUBES
The color of this tube significantly reduces light transmission to protect samples intended for analysis of light sensitive analytes.

Terumo Code	Cap Color	Sample Type	Additive	Fill Volume	Letter Code
T-M	Brick Red	SERUM	None	500µl	Z
T-MG	Cherry Red		Gel/Clot activator	500µl	Z
T-MGA	Amber		Gel/Clot activator	500µl	Z
T-MQK	Lavender	PLASMA	Dipotassium EDTA (0.78mg)	500µl	K2E
T-MLH	Green		Lithium Heparin (12.5IU)	500µl	LH
T-MLHG	Green		Gel/Lithium Heparin (12.5IU)	500µl	LH
T-MPS	Gray		Sodium Fluoride (0.72mg)/Potassium Oxalate (0.58mg)	250µl	FX

Cautions:

- Always observe Universal Precautions for all patients for the safe collection, handling, and disposal of blood samples.
- Dispose of used sharps and materials following the policies and procedures of your facility, as well as federal and local regulations for "sharps disposal".
- Do not reshield used sharps.
- Follow facility protocols and procedures in the event of blood exposure.
- Blood should be collected directly from the skin puncture site; samples collected from a syringe are not recommended.
- Blood should be collected to the fill line indicated on each tube to ensure optimal blood-to-additive ratio. Failure to do so may result in clotting and/or erroneous test results.
- For microscopic examination of a blood film, it is suggested that slides be made directly from the puncture site.

Stability:

- CapiJect® Capillary blood collections tubes are stable if used before the expiration date and stored between 15 to 30°C.
- EDTA tubes should be processed within 4 hours of collection.[1]
- Glycolytic inhibitor tubes stabilize plasma glucose for up to 24 hours at 22 to 25°C.[2]

Materials required but not included:

The following items are required to perform a skin puncture:

1. Alcohol wipes or swab (75%)
2. Gloves
3. Lancet device
4. Sterile, dry gauze
5. Marking pens/labels

Instructions for Use

Aseptic technique, proper skin preparation and continued protection of the site are essential.

Always fill EDTA (lavender cap) tubes first when more than one CapiJect® tube is obtained.

1. After donning gloves, select and prepare site for skin puncture according to facility protocol.
2. Gently twist off cap from the CapiJect® tube and "nest" bottom of tube in the recessed portion of the cap.
3. Holding the CapiJect® collection tube in an upright position, touch collector to the drop of blood. Blood will flow down the collector and into the tube. Caution: Milking the puncture site should be avoided to minimize the potential for hemolysis.
4. Fill the CapiJect® tube to the fill volume noted on the tube. Caution: Overfilling or underfilling of tubes may result in clotting and/or erroneous test results.
5. At completion of blood collection, apply pressure to the puncture site with a sterile gauze pad.
6. Replace cap on CapiJect® tube. All tubes containing an additive (see chart above) must be mixed by gently inverting tube 8-10 times immediately after collection.
7. Dispose of used lancets and contaminated materials into an approved biohazard waste container if this has not already been done.
8. Ensure that patient samples are properly labeled and identified.

Transport and Processing:
Tubes should be transported to the test site as soon as possible after collection.

Clotting times for serum tubes:

Gel tubes – minimum 20 minutes before centrifugation
Non-Gel tubes – minimum 30 minutes before centrifugation; process immediately after centrifugation

Centrifugation:
Tubes to be used for tests requiring serum or plasma must be centrifuged at a minimum relative centrifugal force (RCF) of 1200G for 10 minutes or 3500G for 90 seconds.

Limitations:
Blood collected by skin puncture should only be used for lead screening. Elevated blood lead results obtained on capillary specimens should be considered presumptive and must be confirmed using venous blood.[3]

The laboratory performing the lead analysis should determine the appropriate methodology and tube type used for blood lead testing.

It is the responsibility of each laboratory to determine reference intervals for all analytes based upon the tubes used for skin puncture blood specimens by that laboratory. The clinical laboratory should establish/verify its reference ranges if changing specimen collection tube types and sizes, as this could potentially affect analytic results from patient samples.

Manufactured by: **Terumo Medical Corporation, Elkton, Maryland 21921, USA**

EC REP **Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium**

Symbols

CODE / REF	**Product Code**
	**For Single Use Only**
	**Expiration Date**
LOT	**Lot Number**
	**Latex Free**
IVD	**For In Vitro Diagnostic Use**
	**Read Instructions for Use**
	**Store at**
	**Manufacturer**
EC REP	**Authorized representative in the European Community**

1 NCCLS H4-A4 Procedures and Devices for Collection of Diagnostic Blood Specimens by Skin Puncture: Approved Standard – Fourth Edition, September 1999, Vol. 19, No. 16, page 11.
2 NCCLS H18-A2 Procedures for the handling and processing of blood specimens; Approved Standard – Second Edition, October 1999, Vol. 19, No. 21, page 4.
3 Preventing Lead Poisoning in Young Children. A statement by the Centers for Disease Control – October 1991, U.S. Department of Health and Human Services, p. 41.