English

BAPA tube for T-TAS®01

For Investigational Use Only



18004

CONTENT

50 tubes

Intended use

The BAPA tube for T-TAS 01 is intended to be used for the collection, transport, and storage of blood specimens for use with the T-TAS 01 system.

Summary

BAPA (Benzylsulfonyl-D-argininyl-prolyl-4-amidinobenzylamide), an inhibitor of thrombin and factor Xa, allows anticoagulation of blood without interference with physiological calcium levels.

The specified concentration of BAPA in collected blood is $\geq 50 \,\mu g/mL$.

Blood collection tube

50 x 3 mL tubes containing spray-dried BAPA anticoagulant

Warnings and precautions

- · Investigational Device Instrument de recherche
- · To be Used by Qualified Investigators Only Réservé uniquement à l'usage de chercheurs compétents
- · Human blood should be handled as potentially infectious, and Universal Precautions should be followed.
- · Disposal of all waste material should be in accordance with local, state, and Federal guidelines.
- · Do not use tubes if foreign matter is present in the tube.
- · Do not use tubes after their expiration date.

Precautions for blood collection

- · Use 21 gauge or larger-bore needles (18-20 gauge) for blood collection.
- · Mix the blood by gently inverting the tube 5 times immediately after filling.

Storage and stability

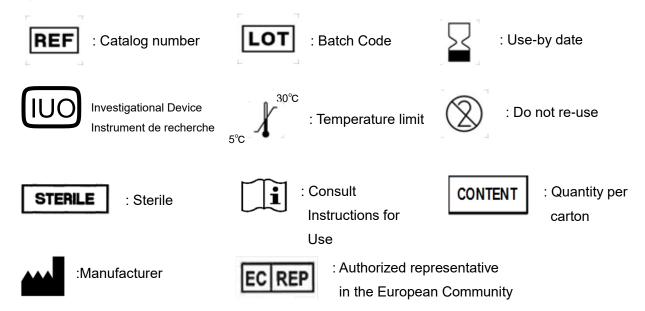
- · Store unused collection tubes at 5 to 30 °C. Avoid exposure to direct sunlight.
- · The product is stable until the expiration date printed on the tube label when stored under these conditions.

Note: Deviation from recommended storage conditions may lead to impairment of the tube quality.

References

For additional information about measurements using the BAPA tube for T-TAS 01, please refer to the T-TAS 01 User Manual and assay package insert(s).

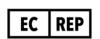
Symbols







FUJIMORI KOGYO CO., LTD. 1-1-1 Koishikawa, Bunkyo-ku, Tokyo



Medical Device Safety Service GmbH Schiffgraben 41 30175 Hannover, Germany



EU Importer
MedEnvoy
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands