

RUO - RESEARCH / INVESTIGATIONAL USE ONLY

INTENDED USE

Inhibitor Tubes provide a pre-determined quantity of a coagulation inhibitor such as dabigatran or rivaroxaban for delivery to a blood, plasma or urine sample in a tube. They allow laboratories to prepare inhibitor samples at any concentration in any biological fluid by using variable volume for use in research, teaching, or other purposes.

INTRODUCTION

DOACs and other anticoagulants are usually provided in freeze dried normal plasmas for reconstitution and use as calibrators or in quality control. Inhibitor Tubes provide an alternative way for laboratories to access such agents for multiple uses. DOACs are provided in 500 ng target quantities and heparin as 0.2 IU. All of them are dried in stabilizing rapidly soluble dot in a tube. Each tube is coloured for simple identification and dissolves within 5 minutes after being mixed in a fluid at room temperature.

CONTENTS OF PRODUCT	Product Code	Target Value per Tube	Colour Code	Pack Size
	X9222-D	500 ng	Blue	12 Dabi-dot Tubes
	X9222-E	500 ng	Yellow	12 Edoxa-dot Tubes
	X9222-B	500 ng	Pink	12 Betrixia-dot Tubes
	X9222-R	500 ng	Light Green	12 Riva-dot Tubes
	X9222-A	500 ng	Dark Green	12 Apixa-dot Tubes
	X9222-H	0.2 IU	Red	12 Heparin Tubes
	X9222-S			12 Tubes- 2 of each DEBRAH

PRECAUTIONS

Inhibitor Tubes are strictly for *in vitro* use. If appropriate test results are not as expected by Inhibitor Tubes, apply appropriate clotting, chromogenic anti factor Xa or anti thrombin assays to obtain specific results. Contact your distributor or manufacturer for technical support.

Store at 2-8°C. Keep dry. Do not use after the expiry date indicated on the label. Treat all clinical material as potentially infectious and dispose of in accordance with local operating regulations. For further information, please refer to Safety Data Sheet and Product Information.

INSTRUCTIONS FOR USE

Method for adding an inhibitor to a liquid sample.

1.	Take the appropriate inhibitor tube from its storage container.
2.	Add 1 ml of citrated blood plasma/urine into each tube.
3.	After standing for 5 minutes, mix thoroughly.
4.	The fluid sample will then contain the targeted value of the inhibitor in 1 ml.

APPLICATION

Plasmas treated with Inhibitor Tubes may be used as positive controls in clotting, chromogenic or other assays. Dilutions can be prepared in pooled normal plasma, blood or other fluids to set up calibration curves. Consensus values can be established from interlaboratory testing surveys.

Samples prepared from Inhibitor Tubes can be used for checking the efficacy of DOAC Stop (1). This agent removes DOACs from test samples relatively specifically (2). Thus, samples prepared with DOACs from Inhibitor Tubes should show restoration to original test results after treatment with DOAC-Stop™. Conversely, results on samples prepared with Heparin Dots should not be modified by DOAC-Stop™.

LIMITATIONS

The agents used in Inhibitor Tubes are not endorsed by the known manufacturers of the indicated agents. The quantity of each compound shown is our "target" value and may vary slightly.

PERFORMANCE CHARACTERISTICS

Repetition testing indicates that activity of inhibitors from Inhibitor Tubes varies by less than +/- 5% for DOACs as tested by the Russells Viper Venom (RVV)-based Go-DOAC™ test (Haematex) and by less than +/- 3% for heparin using APTT (Intrinsic LR) tests. The use of dRVV-based clotting tests for DOACs is strongly recommended as these are more sensitive to DOACs than most other tests.

INDEMNITY NOTICE

Inhibitor Tubes are intended for use in biological fluids. Follow procedures and refer to precautions that may affect the stated or implied claims and performance of this product. Haematex Research Pty Ltd and its agents or distributors are not liable for damages.

REFERENCES

- [1] Simple method for removing DOACs from plasma samples. Exner T, et al. Thrombosis Research. 2018; 16:1028-39.
- [2] Effect of an activated charcoal product (DOAC-Stop™) intended for extracting DOACs on various other APTT-prolonging agents. Exner T, et. al. Clin Chem Lab Med. 2019; 57: 690-696.



Calibration curves obtained for lot #737 using Go-DOAC™ Test #723 15/12/2022.

