



RUO - RESEARCH / INVESTIGATIONAL USE ONLY

## Inhibitor Dots

HTX Products X9222 - D/A/R/E/B/H

### INTENDED USE

Inhibitor "Dots" provide a pre-determined quantity of a coagulation inhibitor such as a DOAC (dabigatran, apixaban, rivaroxaban, edoxaban and betrixaban) or heparin for delivery to a blood, plasma or urine sample on a plastic dipstick. They allow laboratories to prepare inhibitor samples at any concentration in any biological fluid 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 Dots provide an alternative way for laboratories to access such agents for multiple uses. DOACs are provided in 500ng quantities; heparin as 0.3IU, dried in a stabilizing and rapidly soluble film on a narrow dispenser strip. Each inhibitor dot is coloured for simple identification as shown below. The binding agents in the dots total 200ug and have insignificant effect on clotting or other tests when dispersed in 1ml of plasma or blood. Each strip is identified by a label showing lot number, expiry date and inhibitor quantity. Each Dot dissolves within 2 minutes after being immersed in a fluid.

### CONTENTS OF PRODUCT

Product Code	Colour	Pack Size
X9222-S (Sample pack; 2 each of D/A/R/E/B & H)	-----	12 strips
X9222-D (Dabigatran-like, 12 strips)	Blue	500ng
X9222-A (Apixaban-like, 12 strips)	Dark green	500ng
X9222-R (Rivaroxaban-like, 12 strips)	Light green	500ng
X922205-E (Edoxaban-like, 12 strips)	Yellow	500ng
X9222-B (Betrixaban-like, 12 strips)	Pink	500ng
X9222-H (Heparin, 12 strips)	Red	0.3IU

### PRECAUTIONS

Inhibitor strips are strictly for in vitro use. They are mainly intended for spiking blood, plasma or urine samples with anticoagulants. If appropriate test results are not changed as expected by Inhibitor Dots, apply appropriate clotting, chromogenic anti factor Xa or anti thrombin assays to obtain specific results. Contact your distributor or manufacturer for technical support. NB. Australian patent application 2019284125.

Store at 2-8°C. 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

#### Sample preparation:

Follow your usual validated laboratory procedures for preparing blood, citrated plasma or other samples.

#### Method for adding an inhibitor to the sample.

1. Transfer 1ml of citrated blood, plasma or urine to a plastic tube.
2. Select which inhibitor is to be dispersed into this sample. Remove the appropriate strip from its storage container.
3. Dip the inhibitor strip into the fluid so that the round Inhibitor Dot at one end is immersed.
4. Mix for 2 minutes or until the round dot is no longer visible on the strip. Check this visually by dipping in and out of the fluid.
5. The sample will then contain the added stated inhibitor quantity in 1 ml.

### APPLICATION

Plasmas treated with Inhibitor Dots 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.

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

### LIMITATIONS

The agents used in Inhibitor Dots are not endorsed by the known manufacturers of the indicated agents.

### PERFORMANCE CHARACTERISTICS

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

### INDEMNITY NOTICE

Inhibitor Dots 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. Thromb. Res. 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, Ahuja M, Ellwood L. Clin Chem Lab Med. 2019; 57: 690-696.

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