IMPORTANT CHANGE
Please remove the protective film over each inhibitor dot before use.

RUO - RESEARCH / INVESTIGATIONAL USE ONLY

Inhibitor Dots

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

INTENDED USE

Inhibitor "Dots" provide a pre-determined quantity of a coagulation inhibitor such as a DOAC (dabigatran, edoxaban, betrixaban, rivaroxaban, apixaban) 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 (target) quantities; heparin as 0.3Iu, dried in a stabilizing, rapidly soluble film on a narrow dispenser strip. Each inhibitor dot is coloured for simple identification as shown below. The colour and base total 5µg 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 date and inhibitor quantity. Each spot 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/E/B/R/A/H)		12 strips
X9222-D (Dabigatran- like, 12 strips)	Blue	500ng
X9222-E (Edoxaban - like, 12 strips)	Yellow	500ng
X9222-B (Betrixaban - like, 12 strips)	Pink	500ng
X9222-R (Rivaroxaban-like,12 strips)	Light green	500ng
X9222-A (Apixaban - like, 12 strips)	Dark green	500ng
X9222-H (Heparin…… 12 strips)	Red	0.3Iu

PRECAUTIONS

Inhibitor strips are strictly for in vitro use. They are mainly intended for use with blood, plasma or urine samples not containing such agents. 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. Australian patent application 2019284125.

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

Sample preparation:

Inhibitor Dots have been developed for use with citrated plasmas and whole blood or urine. Follow your usual validated laboratory procedures for preparing 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 protective film over each "dot".
3. Dip the appropriate inhibitor strip into the fluid so that the round Inhibitor Dot is immersed.
4. Mix for 2 minutes or until the round spot is no longer visible on the strip. Check this 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 or blood to set up calibration curves.
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. Inhibitor quantities shown are target values. More precise consensus values may be available on request. Note that the marker dyes may influence results of some chromogenic assays.

PERFORMANCE CHARACTERISTICS

Repetition testing indicates that activity of inhibitors from Inhibitor Dots varies by less than +/- 5% for DOACs as tested by the RVV-based "DOAC Test" (Haematex) and by less than +/- 4% for heparin using APTT (Intrinsin LR) 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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