English

INTENDED USE

DOAC-Stop can be used to efficiently extract all types of Direct Oral Anti-Coagulants (DOACs) including dabigatran, edoxaban, betrixaban, rivaroxaban, apixaban and also argatroban from test plasmas with minimal effect on plasma proteins involved in the clotting mechanism. This product is intended for use as an accessory IVD. For professional use only.

INTRODUCTION

Therapeutic uses of DOACs are increasing. DOACs are known to interfere with almost all clotting tests to varying degrees. Specific antidotes for individual DOACs are being developed but are not yet widely available for laboratory use. DOAC-Stop is the first general agent available for solving the diagnostic problems associated with DOACs. After treatment with DOAC-Stop, plasma samples can be analysed for underlying coagulation defects such as factor deficiencies, heparin, lupus anticoagulant or other interfering antibodies [1].

CONTENTS OF PRODUCT	Product Code	Pack Size
	HX9904-100	100 tablets
	HX9904-50	50 tablets

LIMITATIONS

DOAC-Stop may extract low molecular weight compounds resembling DOACs from plasmas. Those affecting coagulation (but administered intravenously, not orally) include argatroban, aprotinin, protamine, hirudin analogues, polymyxin and related cationic compounds [2].

PRECAUTIONS

DOAC Stop is intended for use with plasma samples suspected to contain DOACs. If test results are unchanged by DOAC Stop and DOACs are still suspected to be present, apply appropriate chromogenic anti factor Xa or anti thrombin assays to obtain specific DOAC results. Contact your distributor or manufacturer for technical support.

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

INSTRUCTIONS FOR USE

Sample preparation: DOAC-Stop has been developed for use with citrated plasmas. Follow your validated laboratory procedures for preparing test plasma. Apply the citrated plasma in the procedure below to remove any DOAC if present. Please refer to www.haematex.com/eifu for Instructions for Use (IFU) in other EU Member States languages.

Method for DOAC removal from a test plasma:

1.	Add 1.0mL of citrated test plasma to be treated to a plastic centrifuge tube. *Ideally 1.0mL plasma but a range from 0.5 ml to 1.5 ml is acceptable.*
2.	Add 1 DOAC-Stop mini-tab and mix gently until it has dispersed. Mix for a further 5-10 minutes.
3.	Centrifuge down the particulate matter (for example, 5 minutes at 2000g or 1 minute at 7000g in a microfuge). Do not stop centrifuging too quickly.
4.	The supernatent plasma, now depleted of DOACs can be used directly for testing or can be transferred into a separate plastic tube for frozen storage.

APPLICATION

Plasmas treated with DOAC-Stop can be used for reliable routine assessment of known blood coagulation parameters [3-7]. The degree of shortening induced by DOAC-Stop in a clotting time test depends on the concentration and type of DOAC as well as the on the underlying plasma itself. Clotting time results with DOAC sensitive tests such as dRVVT and APTT tests, may be expressed as ratios of test result before (B) to that obtained after (A) DOAC Stop treatment. The B/A result ranges upward from 1.0 and correlates positively with DOAC concentration depending on which DOAC and test is used [8].

PERFORMANCE CHARACTERISTICS

One mini-tab of DOAC Stop in 1.0mL of normal plasma spiked with 500ng/ml of dabigatran, edoxaban, betrixaban, rivaroxaban or apixaban will remove more than 95% of the DOAC within 5 minutes. There was no effect on the baseline APTTs after 3 hours further incubation. In 92 test plasma samples covering a range of abnormalities, 89 gave definitive results and 3 were equivocal after DOAC-Stop in view of patient complexity [1].

A recent study on 135 DOAC-treated plasmas showed that DOAC Stop was mostly effective in overcoming the effects of dabigatran in 40 cases, apixaban in 38 cases, rivaroxaban 42 cases and edoxaban 15 cases on several thrombophilia screening tests. The incidence of false positive lupus anticoagulants fell from approximately 30% to zero [3]. For additional information, contact your distributor for a copy of the Technical Documentation.

INDEMNITY NOTICE

DOAC-Stop is intended to be used with plasma samples containing DOACs. Follow procedures and refer to precautions that may affect the stated or implied claims and performance of this product. Cellabs, Haematex and its agents or distributors are not liable for damages.

VIGILANCE REPORTING

Vigilance Reporting for EU Member states must be reported without delay, as soon as practicable to the EU Representative, WMDE B. V, Bergerweg 18, 6085 AT Horn, The Netherlands, who will act on behalf of Cellabs Pty Ltd, the Competent Authority (CA) of your country and/or Cellabs Pty Ltd, 7/27 Dale Street, Brookvale, NSW, 2100, Australia or through the website: www.cellabs.com.au.

REFERENCES

[1] Exner T, et al. “Simple method for removing DOACs from plasma samples” Throm Res. 2018; 16: 1028-39.
[2] Exner T, et al. “Effect of an activated charcoal product (DOAC Stop™) intended for extracting DOACs on various other APTT-prolonging agents”. Clin Chem Lab Med. 2019; 57: 690-696.
[3] Favresse J, et al. “Evaluation of the DOAC Stop procedure to overcome the effect of DOACs on several thrombophilia screening tests”. TH Open, 2018; 2: e202-e209.
[4] Platton S, Hunt C. “Influence of DOAC Stop on coagulation assays in samples from patients on rivaroxaban or apixaban”. Int J Lab Haematol. 2019; 41: 227-233.
[5] Jacquemin M, et al. “The adsorption of dabigatran is as efficient as addition of Idarucizumab to neutralize the drug in routine coagulation assays. Int J Lab Hematol. 2018; 40: 442-447”.
[6] Favaloro EJ, et al. “Neutralising rivaroxaban-induced interference in laboratory testing for lupus anticoagulants (LA): A comparative study using DOAC Stop and Andaxanet alpha”. Throm Res. 2019; 180:10-19.
[7] Kopatz WF, et al. “Use of DOAC Stop for the elimination of anticoagulants in the thrombin generation assay”. Throm Res. 2018; 170: 97-101.
[8] Exner T, et al “Clotting tests correlate better with DOAC concentrations when expressed as a “Correction Ratio”; results before/after extraction with the DOAC Stop reagent. Throm Res.2019; 179: 69-72.
[9] Exner T, et al “The effect of DOACs on laboratory tests and their removal to limit interference in functional assays. Int J Lab Hematol. 2020; 42 (Suppl.1): 41-48.

EXPLANATION OF SYMBOLS

	Consult instructions for use	REF	Catalogue number
IVD	*In Vitro* Diagnostic Medical Device	Σ	Contains sufficient for <n> tests
	Temperature limitation		Manufacturer: Cellabs, Unit 7/27 Dale St. Brookvale, NSW 2100, Australia
	Keep Dry	EC REP	EC Representative WMDE B. V, Bergerweg 18, 6085 AT Horn, The Netherlands
LOT	Batch code	Insert version	en LH1.12 29 Aug 2022
	Expiry Date	CE	