

# Certificate of Analysis

**Product:** DOAC-Remove 20 (A) or 50 (B) or 250 (C) tablets

**Art. No.:** 5D-82410A/B/C-RUO

**Lot:** 140106A/B/C

**Expiration Date:** 2027-12-31

**Description:** DOAC-REMOVE™ tablets are intended to be used for removal of Direct Oral Anticoagulant (DOAC) compounds from human citrated plasma samples, including dabigatran, rivaroxaban, apixaban and edoxaban. Also removes argatroban. There is no significant effect on clotting factors.

**FOR IN VITRO USE ONLY. FOR RESEARCH USE ONLY.  
NOT FOR USE IN DIAGNOSTIC PROCEDURES.**

**Presentation:** 20 (A), 50 (B) or 250 (C) tablets in a vial. Ready to use. Contains activated carbon, specially formulated with additives.

**Storage:** Store in a dry place at ambient (15-30°C) in its original packaging.

## Analytical Data:

	<u>Specification</u>	<u>Results</u>
Weight (n=100):	18 - 22 mg/tablet	pass
Rivaroxaban binding:	≥ 1200 ng/mL	pass
Apixaban binding:	≥ 1000 ng/mL	pass
Edoxaban binding:	≥ 1000 ng/mL	pass
Dabigatran binding:	≥ 1200 ng/mL	pass

2021-12-15

Signed,



Urs-Peter Geiger

## DOAC-Remove™

For Removal of DOACs from Plasma Specimens

REF. 5D-82410A-RUO	20 tablets
REF. 5D-82410B-RUO	50 tablets
REF. 5D-82410C-RUO	250 tablets

**FOR IN VITRO USE ONLY. FOR RESEARCH USE ONLY.  
NOT FOR USE IN DIAGNOSTIC PROCEDURES.**

Store at Room Temperature

### INTENDED USE

DOAC-REMOVE™ tablets are intended to be used for removal of Direct Oral Anticoagulant (DOAC) compounds from human citrated plasma samples, including dabigatran, rivaroxaban, apixaban and edoxaban. Also removes argatroban. There is no significant effect on clotting factors.

### COMPOSITION

Activated carbon, specially formulated with additives.

### PRESENTATION

20, 50 or 250 tablets in a vial. Ready to use.

### STORAGE AND HANDLING

Store in a dry place at ambient temperature (15-30°C) in its original packaging. Under these conditions, DOAC-Remove™ can be used until the expiry date printed on the label.

### PROCEDURE

1. Specimens should be prepared and stored in accordance with applicable local guidelines (for the United States, see the CLSI H21-A5 guidelines for further information on collection, handling and storage)<sup>1</sup>.
2. Add one DOAC-Remove™ tablet to 1.0 mL citrated plasma, mix gently for 10 minutes, preferable on a rotating shaker.
3. Centrifuge for 5 minutes at 2500g.
4. Carefully remove the plasma supernatant. Avoid resuspension of the precipitate.
5. Use plasma for coagulation testing or freeze in small aliquots for future testing.

### WARNINGS AND PRECAUTIONS

For In Vitro Use Only.











For Research Use Only. Not for Use in Diagnostic Procedures.

### REFERENCES

*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition; CLSI Document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.*

### Symbol Definition:

Symbols used and signs listed in the ISO 15223-1 standard.

	CE Mark / CE-Kennzeichnung / Marquage CE		Temperature limitation / Temperaturbegrenzung / Températures limites de conservation
	In-vitro diagnostic medical device / In-vitro Diagnostikum / Dispositif médical de diagnostic		See instructions for use / Gebrauchsanweisung beachten / Lire le mode d'emploi
	Catalog number / Bestellnummer / Référence catalogue		Contains sufficient for <n> tests / Genügend für <n> Tests / Suffisant pour <n> tests
	Batch code / Chargenbezeichnung / Désignation du lot		Manufacturer / Hersteller / Fabricant
	Use by / Verwendbar bis / Utilisable jusqu'à		EC Authorized Representative / EU Bevollmächtigter / EC représentant autorisé

### Manufactured For:

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## DP-Filter®

For Removal of DOACs from Plasma Specimens

**REF** 5D-82412-RUO

**FOR IN VITRO USE ONLY. FOR RESEARCH USE ONLY.  
NOT FOR USE IN DIAGNOSTIC PROCEDURES.**

Store at Room Temperature

### DESCRIPTION

One box contains 25 ready-to-use DP-Filter®.

### INTENDED USE

The DP-Filter® is a device for the filtration of citrated plasmas to remove Direct Oral Anticoagulants (DOAC) including dabigatran, edoxaban, apixaban and rivaroxaban at concentrations from 0,000 to 1,000 ng/mL.

### APPLICATION

Aiding hemostasis research laboratories to develop more sophisticated methods for diagnosing hemostatic disorders. The study of blood parameters of patients under DOAC therapy is challenging and may lead to false results. The DP-Filter® is effective in filtering DOAC from citrated plasma providing anticoagulant-free plasma that can be used for testing.

### PROCEDURE

Specimens should be prepared and stored in accordance with applicable local guidelines (for the United States, see the CLSI H21-A5 guidelines for further information on collection, handling and storage). DP-Filter® can be used with frozen plasma after thawing.

1. Add 500 µL of plasma on the upper side of the DP-Filter.
2. Vortex the device.
3. Incubate the device 5 minutes at room temperature.
4. Centrifuge the device 2 minutes at 200g. Plasma must be fully passed through the filter.
5. Remove the upper filter from the device.
6. The collected plasma (free from DOAC) can be used for testing or can be frozen for later analysis.

### STORAGE AND STABILITY

Store in a dry place at ambient temperature (15-30°C) in its original packaging.

### WARNINGS AND PRECAUTIONS

For In Vitro Use Only. For Research Use Only. Not for Use in Diagnostic Procedures.

### REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays Approved Guideline-Fifth Edition, CLSI document H21-A5 (ISBN 1-56238-657-3)
2. Favresse, J. *et al.* Neutralization of biotin interference: preliminary evaluation of the VeraTest Biotin™, VeraPrep Biotin™ and BioT-Filter®. *Clinical Chemistry and Laboratory Medicine (CCLM)*, Volume 58, Issue 8, Pages e130–e133, eISSN 1437-4331, ISSN 1434-6621
3. Lessire S, Dincq A-S, Siriez R, *et al.* Assessment of low plasma concentrations of apixaban in the periprocedural setting. *Int J Lab Hematol.* 2020;00:1–9. <https://doi.org/10.1111/ijlh.13202>
4. Siriez R, Dogné J-M, Gosselin R, Laloy J, Mullier F, Douxfils J. Comprehensive review of the impact of direct oral anticoagulants on thrombophilia diagnostic tests: Practical recommendations for the laboratory. *Int J Lab Hematol.* 2020;00:1–14. <https://doi.org/10.1111/ijlh.13342>



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