

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 $^{\circ}$ C) in its original packaging. Under these conditions, DOAC-RemoveTM can be used until the expiry date printed on the label.

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)¹.
- 2. Add one DOAC-Remove[™] tablet to <u>0.5 to 1.0 mL</u> 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 | CE Mark / CE-Kennzeichnung / Marquage CE | | Temperature limitation / Temperaturbegrenzung / Temperatures limites de |
|-----|--------------------------------------------------------------------------------------------------------------|-------|---------------------------------------------------------------------------------------------------|
| IVD | In-vitro diagnostic medical device / In-vitro Diagnostikum / Dispositif medical de diagnostic in-vitro | []i | See instructions for use / Gebrauchsanweisung beachten / Lire le mode d'emploi |
| REF | Catalog number / Bestellnummer / Référence catalogue | Σ | Contains sufficient for <n> tests / Genügend für <n> Tests / Suffisant pour <n> tests</n></n></n> |
| LOT | Batch code / Chargenbezeichnung / Désignation du lot | *** | Manufacturer / Hersteller / Fabricant |
| | Use by / Verwendbar bis / Utilisable jusqu'à | EC RE | EC Authorized Representative / EU evollmächtigter / EC représentant uutorisé |

Manufactured For:

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