DOAC-Remove™

For Removal of DOACs from Plasma Specimens

REF 5D-82410A 20 pcs.; 5D-82410B 50 pcs.; 5D-82410C 250 pcs.

For *in vitro* use only CE

Intented Use:

DOAC-Remove™ tablets are intended to be used for removal of Direct Oral Anticoagulants (DOACs) compounds from human citrated plasma samples, including dabigatran, rivaroxaban, apixaban and edoxaban. DOAC-Remove™ reduces the false positivity for lupus anticoagulants tests on DOAC-containing plasmas and is useful for reducing interference of DOACs on routine coagulation assays such as APTT, PT, TT, single factors and APC-R. DOAC-Remove™ has no significant effect on coagulation factors.

Composition:

20 mg activated carbon, specially formulated with additives.

Presentation:

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

Storage Conditions:

Store in a dry place at ambient (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 (CLSI H21-A5 guidelines for further information on collection, handling and storage) [1].
2. Add one DOAC-Remove™ tablet to 1.0 mL citrated plasma, mix gently for 5 minutes at 20-25°C, 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 aliquots for future testing.

Performance_Characteristics:

One DOAC-Remove™ tablet will remove more than 95% of DOAC from plasma spiked with 600 ng/mL dabigatran, rivaroxaban, apixaban or edoxaban. If necessary DOAC levels should be remeasured after treatment with DOAC-Remove™ to ensure removal below the limit of detection (LoD). Reference ranges for screening assays derived from normal plasmas treated with DOAC-Remove may aid interpretation[9].

Limitations and Interferences:

Depending on their molecular weight, DOAC-Remove™ also (partially) removes low molecular weight drugs from test plasma like low molecular weight heparin, some unfractionated heparins, argatroban, aprotinin, bivalirudin and protamine. When comparing treated and untreated samples (for example in thrombin generation assays) we recommend centrifugation of both the samples[3]. Residual DOAC interference should be ruled out in case of persisting lupus anticoagulants positive results after treatment with DOAC-Remove™[7].

References:

1) 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.

2) Does in-vitro addition of activated charcoal allow lupus anticoagulant testing with dRVVT in plasma of patients treated with DOAC?: the CAVIAR study. Jessica Valaize, Demagny Julien, Adrien Borgel, Fabienne Nedelec-Gac, Alain Stépanian, Isabelle Gouin-Thibault, Virginie Siguret. ECTH 2018, P215.

3) Use of DOAC Stop for elimination of anticoagulants in the thrombin generation assay. Wil F. Kopatz, Herm Jan M. Brinkman, Joost C.M. Meijersa. Thrombosis Research 170 (2018) 97-101.

4) Interference of DOAC stop and DOAC remove in the thrombin generation assay and coagulation assays. Tinne Monteyne, Pieter De Kesel, Katrien M.J. Devreese. Thrombosis Research 192 (2020), 96-99.

5) Resolving DOAC interference on aPTT, PT, and lupus anticoagulant testing by the use of activated carbon . Frans G, Meeus P, Bailleul E. J Thromb Haemost. 2019;17:1354-1362.

6) DOAC-Remove abolishes the effect of direct oral anticoagulants on activated protein C resistance testing in real-life venous thromboembolism patients. Magdalena Kopytek, Michał Ząbczyk, Krzysztof P. Malinowski, Anetta Undas, Joanna Natorska. Clin Chem Lab Med 2020; 58(3): 430-437.

7) Potential usefulness of activated charcoal (DOAC remove®) for dRVVT testing in patients receiving Direct Oral AntiCoagulants. Georges Jourdi, Maxime Delrue, Alain Stepanian, Jessica Valaize, Geoffrey Foulon-Pinto, Julien Demagny, Jerome Duchemin, Fabienne Nedelec-Gac, Luc Darnige, Emmanuel Curis, Xavier Delavenne, Pascale Gaussem, Virginie Siguret, Isabelle Gouin-Thibault. Thrombosis Research 184 (2019), 86-91.

8) A diagnostic solution for haemostasis laboratories for patients taking direct oral anticoagulants using DOAC-Remove. Sally Cox-Morton, Stephen MacDonald, Will Thomas. Br J Haematol 2019 Nov;187(3):377-385.

9) Effect of DOAC-Remove on coagulation screening assays in samples from patients receiving oral or parenteral anticoagulation. Zahra Al-Qawzai, Chris Dale, Minal Dave, Nada Yartey, Sean Platton. Int J Lab Hematol. 2022; 44:e95-e99

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

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DOAC-Remove™

Zur Entfernung von DOAK's aus Plasmaproben

REF 5D-82410A 20 Stk.; 5D-82410B 50 Stk.; 5D-82410C 250 Stk.

In vitro-Diagnostikum CE

Verwendungszweck:

DOAC-Remove™ Tabletten werden für die Entfernung von direkten oralen Antikoagulanzien (DOAK's) wie Dabigatran, Rivaroxaban, Apixaban und Edoxaban aus zu untersuchendem humanen Citratplasma verwendet. DOAC-Remove™ reduziert die Anzahl falsch positiver Ergebnisse bei Tests auf Lupus Antikoagulanz in Testplasmen die DOAK's enthalten und ist hilfreich bei der Reduzierung von Interferenzen durch DOAK's auf Routine Gerinnungstests wie z.B. APTT, PTZ, TZ, Einzelfaktoren, APC-R. DOAC-Remove™ hat keinen signifikanten Einfluss auf Gerinnungsfaktoren.

Zusammensetzung:

20 mg speziell formulierte Aktivkohle mit Zusatzstoffen.

Packungsinhalt:

20, 50 oder 250 Tabletten in einer Packung. Gebrauchsfertig

Lagerung:

Trocken bei Raumtemperatur (15-30°C) in der Originalverpackung lagern. Unter diesen Bedingungen kann DOAC-Remove™ bis zu dem auf dem Etikett aufgedruckten Verfalldatum verwendet werden.

Testdurchführung:

1. Die Gewinnung und Lagerung der Citratplasma Proben hat gemäß lokaler Vorschriften zu erfolgen (Vorschriften für die Probengewinnung, -handhabung und -lagerung sind im CLSI-Dokument H21-A5 veröffentlicht)[1].
2. 1 Tablette DOAC-Remove™ zu 1,0 mL Probe hinzufügen und 10 Minuten vorsichtig bei 20-25°C durchmischen (z.B. auf einem Rotationsmischer).
3. Für 5 Minuten bei 2500g oder 2 Minuten bei 5000g zentrifugieren.
4. Den Plasmaüberstand vorsichtig abpipettieren. Durchmischung mit dem abzentrifugierten Niederschlag vermeiden.
5. Das so behandelte Probenplasma kann sofort für Gerinnungstests verwendet oder aliquotiert eingefroren werden.

Leistungsmerkmale:

Eine DOAC-Remove™ Tablette entfernt mehr als 95% der DOAK von Plasmen mit bis zu 600 ng/mL Dabigatran, Rivaroxaban, Apixaban oder Edoxaban. Falls notwendig und um die Entfernung der DOAK bis unterhalb deren Nachweisgrenze (LOD) zu bestätigen, kann der DOAK-Gehalt des Testplasmas nach Behandlung mit DOAC-Remove™ gemessen werden. Referenzbereiche von mit DOAC-Remove™ behandelten Normalplasmen können bei der Interpretation von Screening Ergebnissen hilfreich sein[9].

Einschränkungen und Interferenzen:

Abhängig von deren Molekulargewicht, entfernt DOAC-Remove™ auch niedermolekulare Arzneimittel wie niedermolekulare Heparine, einige unfraktionierte Heparine, Argatroban, Aprotinin, Bivalirudin und Protamin aus dem Testplasma. Für den Vergleich von behandelten und unbehandelten Proben (z.B. für den Thrombingenerierungstest) empfiehlt es sich, beide Proben zu zentrifugieren[3] Bei einem, trotz Behandlung des Testplasmas mit DOAC-Remove™, positiven Lupus Antikoagulanz Resultat, sollte eine Interferenz durch verbliebene DOAK Reste ausgeschlossen werden[7].

Referenzen:

1) 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.

2) Does in-vitro addition of activated charcoal allow lupus anticoagulant testing with dRVVT in plasma of patients treated with DOAC?: the CAVIAR study. Jessica Valaize, Demagny Julien, Adrien Borgel, Fabienne Nedelec-Gac, Alain Stépanian, Isabelle Gouin-Thibault, Virginie Siguret. ECTH 2018, P215.

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6) DOAC-Remove abolishes the effect of direct oral anticoagulants on activated protein C resistance testing in real-life venous thromboembolism patients. Magdalena Kopytek, Michał Ząbczyk, Krzysztof P. Malinowski, Anetta Undas, Joanna Natorska. Clin Chem Lab Med 2020; 58(3): 430-437.

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9) Effect of DOAC-Remove on coagulation screening assays in samples from patients receiving oral or parenteral anticoagulation. Zahra Al-Qawzai, Chris Dale, Minal Dave, Nada Yartey, Sean Platton. Int J Lab Hematol. 2022; 44:e95-e99

Symboldefinition:

Die verwendeten Symbole entsprechen den ISO 15223-1 Vorgaben.

CE	CE Mark / CE-Kennzeichnung / Marquage CE		Temperature limitation / Temperaturbegrenzung / Temperatures limites de conservation
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5-DIAGNOSTICS
Research and Diagnostic Solutions. Delivered.

MATERIAL SAFETY DATA SHEET

Product Name: DOAC-REMOVE

Product Reference: 5D-82410A DOAC-REMOVE, 20 tablets

5D-82410B DOAC-REMOVE, 50 tablets

5D-82410C DOAC-REMOVE, 250 tablets

MATERIAL SAFETY DATA SHEET

ENGLISH

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Product identifier

Name	Product number
DOAC-REMOVE, 20 tablets	5D-82410A
DOAC-REMOVE, 50 tablets	5D-82410B
DOAC-REMOVE, 250 tablets	5D-82410C

1.2 Relevant identified uses of the substance or mixture and uses advised against

For *in-vitro* Use Only.

1.3 Details of the manufacturer and supplier of the safety data sheet

5-Diagnostics AG
Heuberg 7
CH-4051 Basel
Switzerland
Tel: +41-61-588 0784
Fax: +41-61-588 0786
E-Mail address: info@5-diagnostics.com

1.4 Emergency telephone number

Tel: +41-61-588 0784 (during normal business hours only)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

2.2 Label elements

The product is not subject to labelling requirements in accordance with current EC guidelines and corresponding national legislation.

2.3 Other hazards

None

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1Substances

Activated Carbon; EC no.: 931-328-0; weight %: <50%; REACH registration no. 01-2119488894-16; other classifications: not applicable.

3.2Other information

Do not inject or ingest.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

If symptoms develop or when in doubt, seek medical attention. Never give anything by mouth to an unconscious person. Do not leave victim unattended.

After inhalation

IF INHALED: Remove victim to fresh air. Keep warm and at rest. If irritation occurs, seek medical attention. If necessary, restore normal breathing through standard first aid measures.

After skin contact

SKIN CONTACT: Wash off immediately with plenty of soap and water. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If skin reaction occurs, seek medical attention.

After eye contact

EYE CONTACT: Rinse immediately with plenty of water for at least 15 minutes holding the eyelids open. If possible. remove contact lenses. Continue to rinse. Seek medical attention preferably an ophthalmologist.

After ingestion

INGESTION: get immediately medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use foam, carbon dioxide (CO2), dry chemical or water spray. Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas

Unsuitable extinguishing media

None

5.2 Special hazard arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO_2); Carbon monoxide (CO)

5.3 Advice for firefighters

In the event of a fire: Wear protective equipment. Self-contained breathing apparatus. Do not breathe fire/explosion fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal protections, protective equipment and emergency procedures

Refer to protective measures listed in section 7 and 8. Avoid dust formation. Ensure adequate ventilation.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Do not place spilled material back in the original container. Avoid dry sweeping and use water spraying or vacuum cleaning systems to prevent airborne dust generation.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handing

Advice on safe handing

For safe product handling, select and apply appropriate prevention and control measures that will reduce to a minimum the intrinsic risk hazard. Design and operate processes, insofar as the state of technology permits, in such a way that dangerous substances may not be released / contact with the skin can be ruled out.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapors. Avoid contact whit eyes and skin. Remove soiled or soaked clothing immediately.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed in a dry, cool, well-ventilated place. Do not store together with strong oxidizing agents. Do not store together with volatile chemicals as they may be adsorbed onto product.

Incompatible materials

Strong oxidizing agents. Strong acids.

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated. Per Article 14.4 of the REACH Regulation no exposure scenario has been developed as the substance is not hazardous.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

No parameters available for monitoring.

Biological limit values

No data available

8.2 Exposure controls

Appropriate engineering controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Any measure taken shall comply with good hygiene practice.

Personal protective equipment

During product handling, wear appropriate protective clothing in compliance with the applicable rules.

Respiratory protection

Approved respirator may be necessary if local exhaust ventilation is not adequate.

Hand/skin protection

During handling, wear appropriate protective gloves. Prior to use, check in any case suitability of protective glove for the specific workplace conditions. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.Protective gloves must be tested and approved under EN374 standard. Replace protective gloves immediately when they become worn and damaged.

Eye / face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Body protection

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Other

No data available

Environmental exposure controls

Prevent further spillage/release of material if safe.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Property	
	5D-82410A/B/C
Appearance	Solid Tablet/Pellet
Color	Black
Odour	Odorless
pH value	NA
Boiling point	NA
Melting point	NA
Decomposition point	NA
Flash point	NA
Auto-ignition temperature	NA
Oxidising properties	NA
Explosive properties	NA

Flammability	NA
Lower flammability or explosive limits	NA
Upper flammability or explosive limits	NA
Vapour pressure	NA
Vapour density	NA
Evaporation rate	NA
Relative density	NA
Solubility in water	NA
Solubility	NA
Partition coefficient: n-octano/water	NA
Viscosity	NA
Other information	NA

NA: Not Applicable

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reactions known if handled in compliance with applicable provisions/under normal conditions of use.

10.2 Chemical stability

The preparation is stable if handled and stored as recommended under section 7.

10.3 Possibility of hazardous reactions

None if used for the intended purpose.

10.4 Conditions to avoid

None if used for the intended purpose.

10.5 Incompatible materials

Strong oxidizing agents, strong acids

10.6 Hazardous decomposition products

None if used for the intended purpose.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Property	
	5D-82410A/B/C
Acute oral toxicity	ND
Acute dermal toxicity	ND

Acute inhalational toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/eye irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Reproductive toxicity	Not classified
Carcinogenicity	Not classified
Specific target organ toxicity : - **Single exposure** - **Repeated exposure**	Not classified
Aspiration hazard	No aspiration hazard is expected

No component of this product present at levels greater than or equal to 0.1 % is identified as probable, possible or confirmed human carcinogen by IARC.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity	5D-82410A/B/C
Fish toxicity - **Acute** - **Chronic**	Non toxic
Daphnia toxicity - **Acute** - **Chronic**	Non toxic
Algae toxicity - **Acute** - **Chronic**	ND
Bacteria toxicity - **Acute** - **Chronic**	ND

ND: No data available.

12.2 Persistence and degradability

No data available.

12.3 Bio-accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Assessment	5D-82410A/B/C
PBT assessment	Does not fulfill the criteria for PBT
vPvB assessment	Does not fulfill the criteria for vPvB

12.6Other adverse effects

No data available.

SECTION 13: WASTE DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose of waste in compliance with national rules and consultation with environmental services. The waste code is established in consultation with your regional waste disposer.

Packaging

Empty properly packaging. Completely emptied packaging or practically empty packaging containing residues shall be disposed of properly in consultation with your regional waste disposer.

SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

This MSDS file is comply to the requirements described on the Regulation (EC) No 1907/2006 (REACH) and 1272/2008 (CLP).

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

16.1 Key literature references and sources for data

Regulation EC 1907/2006(REACH), Regulation (EC) 1272/2008 (CLP) its current version.

Regulations concerning the International Carriage of Dangerous Goods according to ADR, RID, IMDG, IATA in their current version.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section of this SDS.

The above information is based on our present-day knowledge and experience. The information provided above is not a technical specification and does not guarantee any properties or performance and does not represent any contractual relationship.

5-Diagnostics and its appointed agents/distributors or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.

16.2 Abbreviations and acronyms

ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road

CLP: European Regulation on Classification, Labelling and Packaging of Substances and Mixtures

CMR : cancerogen mutagen reprotoxic

IATA-DGR: International Air Transport Association - Dangerous Goods Regulations

IMDG: International Maritime Dangerous Goods code

NIOSH: National Institute for Occupational Safety and Health (NIOSH) in the U.S.

PBT: Persistent, Bioaccumulative, Toxic

ReaCH: European Union Regulation on Registration, Evaluation, Authorization and restriction of CHemicals

RID: International Rule for Transport of Dangerous Substances by Rail

vPvB: very Persistent, very Bioaccumulative