

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



Intended 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 or 2 minutes at 5000g.
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 interpretation⁹.

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 samples³. 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. J. Valaize, J. Demagny, A. Borgel, F. Nedelec-Gac, A. Stépanian, I. Gouin-Thibault, V. Siguret. ECTH 2018, P215.
- 3) Use of DOAC Stop for elimination of anticoagulants in the thrombin generation assay. W.F. Kopatz, H.J.M. Brinkman, J. C.M. Meijers. Thrombosis Research 170 (2018) 97-101.
- 4) Interference of DOAC stop and DOAC remove in the thrombin generation assay and coagulation assays. T. Monteyne, P. De Kesel, K. 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, Bailleur 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. M. Kopytek, M. Ząbczyk, K. P. Malinowski, A. Undas, J. Natarska. 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. G. Jourdi, M. Delrue, A. Stepanian, J. Valaize, G. Foulon-Pinto, J. Demagny, J. Duchemin, F. Nedelec-Gac, L. Darnige, E. Curis, X. Delavenne, P. Gaussem, V. Siguret, I. Gouin-Thibault. Thrombosis Research 184 (2019), 86-91.
- 8) A diagnostic solution for haemostasis laboratories for patients taking direct oral anticoagulants using DOAC-Remove. S. Cox-Morton, S. MacDonald, W. 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. Z. Al-Qawzai, C. Dale, M. Dave, N. Yartey, S. Platton. Int J Lab Hematol. 2022; 44:e95-e99

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 in-vitro		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 / Sufficient pour <n> tests
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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



Verwendungszweck:

DOAC-Remove™ Tabletten werden für die Entfernung von direkten oralen Antikoagulanzen (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 Antikoagulanzen 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 sein⁹.

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 zentrifugieren³ Bei einem, trotz Behandlung des Testplasmas mit DOAC-Remove™, positiven Lupus Antikoagulanzen Resultat, sollte eine Interferenz durch verbliebene DOAK Reste ausgeschlossen werden⁷.

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. J. Valaize, J. Demagny, A. Borgel, F. Nedelec-Gac, A. Stépanian, I. Gouin-Thibault, V. 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. M. Kopytek, M. Ząbczyk, K. P. Malinowski, A. Undas, J. Natarska. 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. G. Jourdi, M. Delrue, A. Stepanian, J. Valaize, G. Foulon-Pinto, J. Demagny, J. Duchemin, F. Nedelec-Gac, L. Darnige, E. Curis, X. Delavenne, P. Gaussem, V. Siguret, I. Gouin-Thibault. Thrombosis Research 184 (2019), 86-91.
- 8) A diagnostic solution for haemostasis laboratories for patients taking direct oral anticoagulants using DOAC-Remove. S. Cox-Morton, S. MacDonald, W. 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. Z. Al-Qawzai, C. Dale, M. Dave, N. Yartey, S. Platton. Int J Lab Hematol. 2022; 44:e95-e99

Symboldefinition:

Die verwendeten Symbole entsprechen den ISO 15223-1 Vorgaben.

	CE Mark / CE-Kennzeichnung / Marquage CE		Temperature limitation / Temperaturbegrenzung / Temperatures limites de conservation
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DOAC-Remove™

Pour l'élimination des DOACs des échantillons de plasma

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

Pour usage *in vitro* uniquement



Utilisation prévue:

Les comprimés DOAC-Remove™ sont destinés à être utilisés pour éliminer les composés des anticoagulants oraux directs (DOAC) des échantillons de plasma citraté humain, notamment le dabigatran, le rivaroxaban, l'apixaban et l'edoxaban. DOAC-Remove™ réduit la fausse positivité des tests d'anticoagulants lupiques sur les plasmas contenant des DOAC et est utile pour réduire l'interférence des DOAC sur les tests de coagulation de routine tels que le TCA, le TP, le TT, les facteurs simples et l'APC-R. DOAC-Remove™ n'a pas d'effet significatif sur les facteurs de coagulation.

Composition:

20 mg de charbon activé, spécialement formulé avec des additifs.

Conditionnement:

20, 50 ou 250 comprimés dans un flacon. Prêt à l'emploi.

Conditions de stockage:

Conserver dans un endroit sec à température ambiante (15-30°C) dans son emballage d'origine. Dans ces conditions, DOAC-Remove™ peut être utilisé jusqu'à la date de péremption imprimée sur l'étiquette.

Procédure:

1. Les échantillons doivent être préparés et conservés conformément aux directives locales applicables (directives CLSI H21-A5 pour de plus amples informations sur la collecte, la manipulation et le stockage) ¹.
2. Ajouter un comprimé DOAC-Remove™ à 1.0 ml de plasma citraté, mélanger doucement pendant 5 minutes à 20-25°C, de préférence sur un agitateur rotatif.
3. Centrifuger 5 minutes à 2500g ou 2 minutes à 5000g.
4. Retirer avec précaution le plasma surnageant. Eviter la mise en suspension du précipité.
5. Utiliser le plasma pour les tests de coagulation ou le congeler en aliquote pour des tests ultérieurs.

Caractéristiques de performance:

Un comprimé DOAC-Remove™ élimine plus de 95% des DOAC d'un plasma supplémenté avec 600 ng/ml de dabigatran, rivaroxaban, apixaban or edoxaban. Si nécessaire, les niveaux de DOAC doivent être remesurés après traitement avec le DOAC-Remove™ afin de s'assurer de l'élimination du produit en dessous de la limite de détection. Les gammes de références pour les tests de dépistage dérivées de plasmas normaux traités avec le DOAC-Remove™ peuvent faciliter l'interprétation ⁹.

Limitations et interférences:

En fonction de leur poids moléculaire, les comprimés DOAC-Remove™ éliminent également (partiellement) les médicaments de faible poids moléculaire du plasma testé comme l'héparine de bas poids moléculaire, certaines héparines non fractionnées, l'argatroban, l'aprotinine, la bivalirudine et la protamine. Lors de la comparaison











d'échantillons traités et non traités (par exemple dans les tests de génération de thrombine) nous recommandons de centrifuger les deux échantillons ³. Une interférence résiduelle des DOACs doit être exclue en cas de résultats positifs persistants aux anticoagulants lupiques après traitement par DOAC-Remove™ ⁷.

Références:

- 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. J. Valaize, J. Demagny, A. Borgel, F. Nedelec-Gac, A. Stépanian, I. Gouin-Thibault, V. Siguret. ECTH 2018, P215.
- 3) Use of DOAC Stop for elimination of anticoagulants in the thrombin generation assay. W.F. Kopatz, H.J.M. Brinkman, J. C.M. Meijers. Thrombosis Research 170 (2018) 97-101.
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Définition des symboles:

Symboles utilisés et signes listés dans le standard ISO 15223-1.

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DOAC-Remove™

Per l'eliminazione dei DOACs dai campioni di plasma

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

Solo per l'uso *in vitro*



Uso previsto:

Le pastiglie DOAC-Remove™ sono destinate a essere utilizzate per rimuovere gli anticoagulanti orali diretti (DOAC) da campioni di plasma umano citratato, compresi dabigatran, rivaroxaban, apixaban ed edoxaban. DOAC-Remove™ reduce la falsa positività dei tests per il lupus anticoagulante su plasmi contenenti DOAC ed è utile per ridurre l'interferenza dei DOAC sui test di coagulazione di routine come APTT, PT, TT, fattori semplici e APC-R. DOAC-Remove™ non ha effetti significativi sui fattori di coagulazione.

Composizione:

20 mg de carbone attivato, appositamente formulato con additivi.

Confezione:

20, 50 o 250 compresse in un flacone. Pronto all'uso.

Condizioni di conservazione:

Conservare in un luogo asciutto a temperatura ambiente (15-30°C) nella confezione originale. In queste condizioni, DOAC-Remove™ può essere utilizzato fino alla data di scadenza riportata sull'etichetta.

Procedura:

1. I campioni devono essere preparati e conservati in conformità alle linee guida locali applicabili (guigelines CLSI H21-A5 per ulteriori informazioni su raccolta, manipolazione e conservazione)¹.
2. Aggiungere una pastiglia di DOAC-Remove™ a 1.0 ml di plasma citrato, mescolare delicatamente per 5 minuti a 20-25°C, preferibilmente su un agitatore rotante.
3. Centrifugare per 5 minuti a 2500g o 2 minuti a 5000g.
4. Rimuovere con cautela il plasma surnatante. Evitare di sospendere il precipitato.
5. Utilizzare il plasma per i tests de coagulazione o congelarlo in aliquote per analisi future.

Caratteristiche di performance:

Una pastiglia di DOAC-Remove™ rimuove piu del 95% del DOAC dal plasma con 600 ng/ml de dabigatran, rivaroxaban, apixaban o edoxaban. Se necessario, i livelli di DOAC devono essere rimisurati dopo il trattamento con DOAC-Remove™ per garantire la rimozione del prodotto al di sotto del limite di rilevamento. Gli intervalli di riferimento per i test di screening derivati da plasma normale trattato con DOAC-Remove™ possono aiutare l'interpretazione⁹.

Limitazioni e interferenze:

A seconda del loro peso molecolare, DOAC-Remove™ rimuove (parzialmente) anche i farmaci a basso peso molecolare dal plasma in esame, come l'éparina a basso peso molecolare, alcune eparine non frazionate, argatroban, aprotinina, bivalirudina e protamina. Quando si confrontano campioni trattati e non trattati (ad esempio nei test di generazione di trombina), si raccomanda la centrifugazione di entrambi i campioni³. L'interferenza residua del DOAC deve essere











esclusa in caso di risultati positivi al lupus anticoagulante dopo il trattamento con DOAC-Remove™⁷.

Referenze:

- 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.
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Definizione dei simboli:

Simboli utilizzati e segni elencati nella norma ISO 15223-1.

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DOAC-Remove™

Voor het verwijderen van DOAC's uit plasmamonsters

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

Uitsluitend voor *in vitro* gebruik



Beoogd gebruik:

DOAC-Remove™ tabletten zijn bedoeld voor het verwijderen van directe orale anticoagulantia (DOAC's), waaronder dabigatran, rivaroxaban, apixaban en edoxaban, uit menselijke gecitrateerde plasmamonsters. DOAC-Remove™ vermindert het aantal vals-positieven voor Lupus-anticoagulanstesten op plasma's die een DOAC bevatten en is nuttig voor het verminderen van interferentie van DOAC's op routine stollingstests zoals APTT, PT, TT, afzonderlijke factoren en APC-R. DOAC-Remove™ heeft geen significant effect op stollingsfactoren.

Samenstelling:

20 mg actieve kool, speciaal geformuleerd met additieven.

Presentatie:

20, 50 of 250 tabletten per verpakking. Klaar voor gebruik.

Bewaring:

Bewaren op een droge plaats bij kamertemperatuur (15-30°C) in de oorspronkelijke verpakking. Onder deze omstandigheden kan DOAC-Remove™ worden gebruikt tot de vervaldatum die op het etiket staat.

Procedure:

1. Monsters moeten worden voorbereid en opgeslagen volgens de geldende lokale richtlijnen (CLSI H21-A5 richtlijnen voor meer informatie over afname, behandeling en opslag) ¹.
2. Voeg één DOAC-Remove™ tablet toe aan 1,0 mL gecitrateerd plasma, meng voorzichtig gedurende 5 minuten bij 20-25°C, bij voorkeur op een roterend schudapparaat.
3. Centrifugeer gedurende 5 minuten bij 2500g of 2 minuten bij 5000g.
4. Verwijder voorzichtig het plasma supernatant. Vermijd dat het precipitaat terug in oplossing komt.
5. Gebruik het plasma voor stollingstests of vries het in porties in voor later gebruik.

Prestatiekenmerken:

Eén DOAC-Remove™ tablet verwijdert meer dan 95% van DOAC uit plasma gespiked met 600 ng/mL dabigatran, rivaroxaban, apixaban of edoxaban. Indien nodig moeten DOAC-spiegels opnieuw worden gemeten na behandeling met DOAC-Remove™ om te garanderen dat tot onder de detectiegrens (LoD) verwijderd wordt. Referentiewaarden voor screeningstests afgeleid van normale plasma's behandeld met DOAC-Remove™ kunnen helpen bij de interpretatie ⁹.

Beperkingen en interferenties:











Afhankelijk van hun molecuulmassa verwijdert DOAC-Remove™ ook (gedeeltelijk) geneesmiddelen met een laag moleculaire massa, zoals laagmoleculaire heparine, sommige ongefractioneerde heparines, argatroban, aprotinine, bivalirudine en protamine, uit testplasma. Bij het vergelijken van behandelde en onbehandelde monsters (bijvoorbeeld bij trombinegeneratietests) raden we aan beide monsters te centrifuger³. Resterende DOAC-interferentie moet worden uitgesloten in geval van aanhoudende positieve Lupus-

anticoagulans resultaten na behandeling met DOAC-Remove™⁷.

Referenties:

- 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. J. Valaize, J. Demagny, A. Borgel, F. Nedelec-Gac, A. Stépanian, I. Gouin-Thibault, V. Siguret. ECTH 2018, P215.
- 3) Use of DOAC Stop for elimination of anticoagulants in the thrombin generation assay. W.F. Kopatz, H.J.M. Brinkman, J. C.M. Meijers. Thrombosis Research 170 (2018) 97-101.
- 4) Interference of DOAC stop and DOAC remove in the thrombin generation assay and coagulation assays. T. Monteyne, P. De Kesel, K. 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. M. Kopytek, M. Ząbczyk, K. P. Malinowski, A. Undas, J. Natarska. 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. G. Jourdi, M. Delrue, A. Stepanian, J. Valaize, G. Foulon-Pinto, J. Demagny, J. Duchemin, F. Nedelec-Gac, L. Darnige, E. Curis, X. Delavenne, P. Gaussem, V. Siguret, I. Gouin-Thibault. Thrombosis Research 184 (2019), 86-91.
- 8) A diagnostic solution for haemostasis laboratories for patients taking direct oral anticoagulants using DOAC-Remove. S. Cox-Morton, S. MacDonald, W. 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. Z. Al-Qawzai, C. Dale, M. Dave, N. Yartey, S. Platton. Int J Lab Hematol. 2022; 44:e95-e99.

Verklaring van de symbolen:

	CE Mark / CE-Kennzeichnung / Marquage CE		Temperature limitation / Temperaturbegrenzung / Temperatures limites de conservation
	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
	Catalog number / Bestellnummer / Référence catalogue		Contains sufficient for <n> tests / Genügend für <n> Tests / Sufficient 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



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