

Herzlich willkommen

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Best Practice  
mit der DOASENSE GmbH und Baier Digitaldruck

# Projektmanagement – Messe / Entwicklung Corporate Identity

## **Verantwortliche**

### **bei der DOASENSE GmbH**

Konzeption: Prof. Dr. med. Job Harenberg – Geschäftsführer  
Dr. Frieder Loesel – Geschäftsführer  
Dr. med. Uwe Spannagel – Medizinischer Berater

### **bei Baier Digitaldruck**

Konzeption und Gestaltung:  
Karin Schell – Satz, Layout, Grafik

Für den ISTH-Kongress in Berlin 2017 und für zukünftige Marketing-Vorhaben der DOASENSE GmbH wurden ein professionelles und einheitliches Erscheinungsbild, ein Messestand sowie verschiedene Unterlagen dazu benötigt.

## Ausgeführte Mediendienstleistungen:

- **Messestand** von der Planung bis zum Auf- und Abbau
- **Logoüberarbeitung**
- **Schaffung eines einheitlichen Corporate Designs**
- **Akzidenzdrucksachen wie Poster, Flyer, Notizblocks, Visitenkarten etc.**
- **Gestaltung und Produktion von Musterverpackungen für die Messe**
- **Grafische Entwicklung und Reinzeichnung von Piktogrammen**
- **Elektronisches, personalisiertes Rundmailing**

# Der Messestand

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## Projektmanagement

als Rundum-Sorglos-Paket von der Planung über Auf- und Abbau bis hin zum Organisieren des Caterings

### Leistungen im Einzelnen:

- Projektleitung
- technische Planung
- Gestaltung vom 1. Entwurf bis zur Erstellung der Druckdaten
- Produktion (Schneideplots, Grafikbanner, Akzidenzdruck, Licht-Installationen etc.)
- Ausstattung Mobiliar (Deckenkubus, Barhocker, Regale, Stühle, Tische etc.) zur Miete bzw. zum Kauf
- IT-Equipment zur Miete bzw. zum Kauf
- Transport zur Messe
- Retoure im Anschluss an die Veranstaltung
- Auf- und Abbau
- Catering (Gestellung Jura-Kaffeemaschine, Bezug Getränke, Gebäck / Salzgebäck, Einweggeschirr etc.)



# Der Messestand

## Raumaufteilung / Grundriss

3D-Ansichten für Aufteilungs-  
und Vermaßungsskizze

4,64 qm Raum für  
Garderobe, Lager,  
Kaffeemaschine etc.

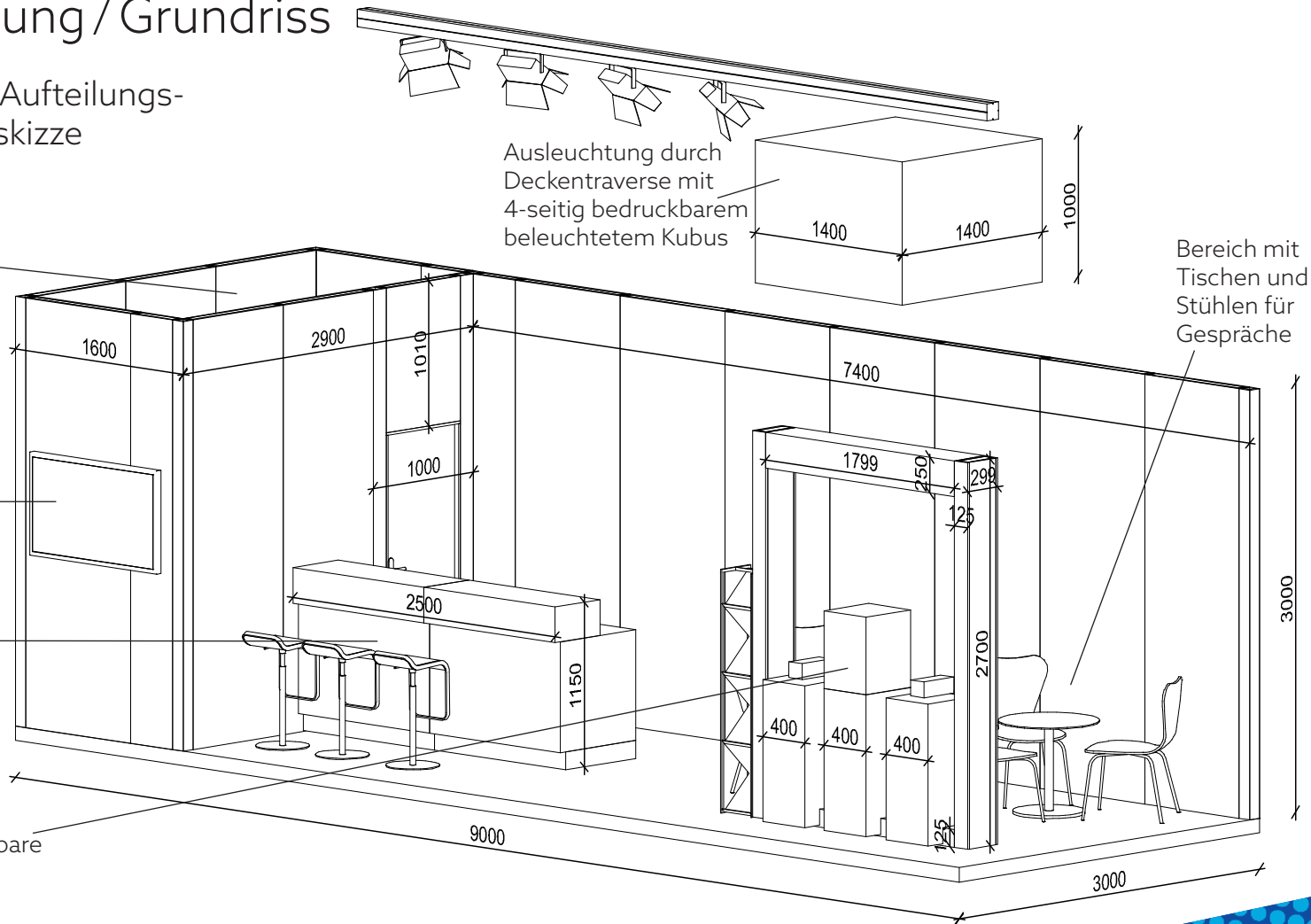
Monitor

Barbereich

abschließ- und beleuchtbare  
Vitrinen für Teststreifen

Ausleuchtung durch  
Deckentraverse mit  
4-seitig bedruckbarem  
beleuchtetem Kubus

Bereich mit  
Tischen und  
Stühlen für  
Gespräche



# Der Messestand

## Gestaltung

Vom Grobkonzept vorab (rechts) bis zum finalen Entwurf (unten) in 3D-Ansicht aus verschiedenen Perspektiven





## Umsetzung

Die Bilder zeigen den Aufbau des Messestands auf dem ISTH Congress in Berlin im Juli 2017 inkl. Anschluss von Beleuchtung und Elektronik.

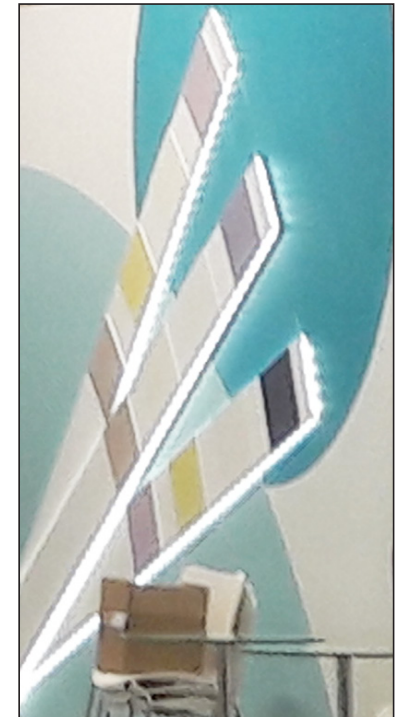
Alle Farbflächen (z. B. Theke und Vitrinengehäuse) sowie die Rückwände wurden mit Digitaldruckfolie in matter Optik kaschiert.



## Ergebnis: Das Produkt im Focus

Ein besonderer Eyecatcher waren die „Teststreifen“ (Format: ca. 4,20 m x 1,70 m). Sie wurden aus drei Lagen Hartschaummateriale gebaut, mit Acrylglas

verblendet und direkt auf die Rückwand montiert. Die Hinterleuchtung des Objekts wurde durch in Reihe geschaltete 12 Volt LED-Ketten erreicht.





## Überarbeitung des Logos – Corporate Design

inkl. Anfertigung eines Corporate-Design-Leitfadens zur einheitlichen Nutzung von Logo, Hausschrift, Farben etc.

Logo

Logo in combination with background—only on white or halftone of „Pantone 312 C“ (max. 45 %)

Fonts

Open Sans Light headlines and continuous text  
 Open Sans Light Italic markup text, quotes  
 Open Sans Semibold markup of complete paragraphs

Line spacing

Headlines font size x factor 1.0 to 1.1 e.g. 36 pt / 39.6 pt  
 Lorem ipsum dolor sit amet ...

Continuous text font size x factor 1.25 e.g. 9 pt / 11.25 pt  
 Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nidi ut aliquip ex ea commodo consequat.

Primary colors

CMYK ISO Coated v2 (EC)	C 73 % M 0 % Y 20 % K 0 %	C 33 % M 0 % Y 9 % K 0 %	C 0 % M 0 % Y 0 % K 0 %	C 0 % M 0 % Y 0 % K 100 %
RGB sRGB IEC61966-2.1	R 0 G 171 B 201	R 182 G 223 B 234	R 255 G 255 B 255	R 26 G 26 B 24

### Guideline Corporate Design

Logo, fonts and colors

Stand 21.06.2017

# Gestaltung und Layout

## Teaser-Motiv für Symposiums-Hinweis

Entwicklung eines Teaser-Motivs und Anpassung an verschiedene Formate für Druck und Online-Verwendung



Mailing-Header 1200 Pixel x 300 Pixel



Online-Hinweis 540 Pixel x 396 Pixel



Roll Up 0,8 m x 1,6 m

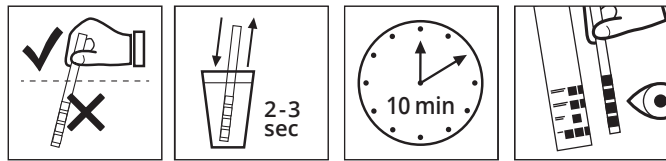


Großbanner 2,5 m x 2,8 m

## Tabellen, Piktogramme und Grafiken

Einheitliches Layout für Infoposter mit Gestaltung übersichtlicher Tabellen für ein schnelleres Erfassen schwieriger Inhalte

Aufbereiten und Entwickeln von leicht verständlichen Piktogrammen für Gebrauchsanweisung



R. Schreiner<sup>1</sup>  
S. Hehlens<sup>1</sup>  
C. Giese<sup>1</sup>  
H.-J. Roth<sup>1</sup>  
R. Krämer<sup>2</sup>  
J. Harenberg<sup>4,5</sup>

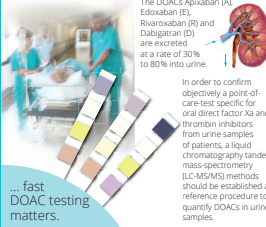
## Determination of Rivaroxaban, Apixaban, Edoxaban and Dabigatran by liquid chromatography-tandem mass-spectrometry and chromogenic assays from urine samples of patients

<sup>1</sup> Medical Service Center Dr. Limbach and Colleagues, Heidelberg, Germany  
<sup>2</sup> Institute of Biometry and Statistics, Medical Faculty Mannheim, Heidelberg University, Heidelberg, Germany  
<sup>3</sup> Inorganic Chemistry Institute, Heidelberg University, Heidelberg, Germany  
<sup>4</sup> Faculty of Medicine, Heidelberg University, Heidelberg, Germany | <sup>5</sup> DOAENSE GmbH, Heidelberg, Germany

**Aim** To develop a LC-MS/MS method for DOACs in urine and evaluate the analytical performance and to compare LC-MS/MS to chromogenic substrate (CS) assays from urine samples of patients treated with A, R and D.

### Objectives

When every minute counts...



The determination of the absence or presence of direct oral anticoagulants (DOACs) may be required in patients' emergency situations.

The DOACs Apixaban (A), Edoxaban (E), Rivaroxaban (R) and Dabigatran (D) are excreted at a rate of 30% to 80% into urine.

In order to confirm objectively a point-of-care-test specific for oral direct factor Xa and thrombin inhibitors from urine samples of patients, a liquid chromatography-tandem mass-spectrometry (LC-MS/MS) methods should be established as reference procedure to quantify DOACs in urine samples.

### Methods

Urine samples were analyzed with ACQUITY H-Class UPLC System, Xevo TQ-S Mass Spectrometer, ACQUITY UPLC CSH C18 Column (Waters) and Responder D4 as internal standard.

Samples were eluted with gradients of ammoniumformiate pH 3.5 and methanol. Artificial urine was spiked with up to 10 µg/ml of DOACs to evaluate the method.

Purified A, E, R and D were obtained from Toronto Research Chemicals, Canada.

The method was validated using urine samples from patients (n=29 or 30) treated with A (5 mg bid), R (20 mg o.d.), D (110 mg or 150 mg bid) and controls.

DOAC activity from patients' urine samples were determined by anti-factor Xa Coamatic® (Haemochrom) and anti-thrombin S2238 chromogenic substrate (CS) (Chromogenic) assays.

Metabolites M1, M5, M7, M9, M11 of Rivaroxaban were determined from patients' urine samples by LC-MS/MS.

SAS release 9.3 program was used for statistical analysis.

The study was approved by the Ethics Committee II of Heidelberg University. Patients gave written informed consent.

### Conclusions

LC-MS/MS may serve as the gold standard method for development of a point-of-care-test from patients' urine samples to determine DOACs.

Metabolites of Rivaroxaban may be detected up to 20% for the aXa activity found in the urine.

### Results

The elution profile of the DOACs in urine samples using the LC-MS/MS method is shown in Fig. 1.

The linearity of the LC-MS/MS method ranged from 0 to 1000 µg/L for A, E, R, and D (Fig. 2).

Lower Limit of Detection (LLOD) between 0.1 and 2.0 µg/L, Lower Limit of Quantification (LLOQ) 0.4 and 3.5 µg/L (Tab. 1).

Intra- and inter-assay coefficients of variations (CV) were both between 2% and 11% (each n=8 determinations, Tab. 2).

Background noise of the LC-MS/MS methods in patients' urine samples of A, R and D corresponded to 5.3 ± 6.7 µg/L, 0.4 ± 0.2 µg/L, 1.2 ± 0.2 µg/L (Tab. 3).

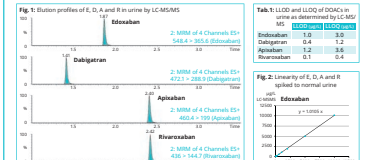
Values of CS assays in controls were < 120 µg/L for all DOACs (Tab. 3).

The results from urine samples of DOACs patients and statistical analysis are given in Tab. 3.

The total concentrations of the metabolites of R in urine samples was 568 ± 992 µg/L (mean, SD, Tab. 3).

Concentrations of metabolites of R and Rivaroxaban correlated between 0.70 and 0.96, all p < 0.0001).

The amount of all metabolites reduced the difference between activity and concentration of R by 20% (p < 0.0001).



**Tab. 1: LLOD and LLOQ of DOACs in urine as determined by LC-MS/MS (n=8 determinations)**

DOAC	LLOD (µg/L)	LLOQ (µg/L)
Edoxaban	0.1	0.4
Dabigatran	0.1	0.4
Apixaban	0.1	0.4
Rivaroxaban	0.1	0.4

**Tab. 2: Intra- and inter-assay variability of the LC-MS/MS method for determination of rivaroxaban concentration rates of DOACs in urine**

DOAC	Concentration (µg/L)	Intra-assay CV (%)	Inter-assay CV (%)
Edoxaban	1.9	5.8	2.1
Dabigatran	2.0	6.2	4.0
Apixaban	2.3	4.5	4.5
Rivaroxaban	1.5	5.9	3.2

**Tab. 3: Concentration and activity of DOACs in patients' urine samples, determined by LC-MS/MS and CS assays and compared with total and Rivaroxaban metabolites. Metabolites of Rivaroxaban by total activity in urine samples, all values are in µg/L.**

DOAC	Concentration (µg/L)	Activity (µg/L)	Metabolites (µg/L)
Apixaban	1649 ± 3420	3538 ± 3628	0.6344 ± 0.0956
Edoxaban	292 ± 222	277 ± 212	0.088 ± 0.011
Metabolites	568 ± 992	74 ± 115	0.020 ± 0.025
Rivaroxaban	157 ± 248	47 ± 115	0.020 ± 0.025
Dabigatran	565 ± 388	583 ± 452	0.082 ± 0.088
Control A, R, D	10	10	10

### Financial support / address

The research was supported by Doaense GmbH. Correspondence to: Prof. Dr. Job Harenberg, DOAENSE GmbH, Waldstr. 102, D-69123 Heidelberg, j.harenberg@doaense.de, www.doaense.de

The scientific work was supported by Doaense GmbH and Rosny Foundation (photographs by LW). Prof. Dr. Job Harenberg, DOAENSE GmbH, Waldstr. 102, D-69123 Heidelberg, info@doaense.de, www.doaense.de

## of point-of-care tests of patients on therapy with Rivaroxaban and Dabigatran

Germany | DOAENSE GmbH, Heidelberg, Germany  
Heidelberg University, Heidelberg, Germany  
Germany

### of-care-test taken from urine samples of patients R and Dabigatran (D).

Observers assigned always the color "normal" to this pad with few exceptions (dark urine, not influencing the color of pads 3 and 4).

Lower pad (Fig. 1 and 2) shows color of urine sample. Observers assigned the color "normal" to this pad (data not shown).

Table 2 shows the results of the statistical analysis of the assessment of the colors of episodes from urine samples of patients and controls (not 1).

Table 3 shows the results of the statistical analysis of the assessment of the colors of episodes from urine samples of patients and controls (not 1).

Table 3 shows the concentrations of A, R, and D and of controls are given from the urine samples of the patients - mean value, standard deviation (sd), coefficient of variation (CV) and number (N).

**Tab. 1: Results of the optical assessment of the colors of urine samples after incubation on DOAC Dipsticks as negative and positive of control groups and patients treated with A, R and D.**

Patient	Edoxaban		Dabigatran		Apixaban		Rivaroxaban	
	neg.	pos.	neg.	pos.	neg.	pos.	neg.	pos.
Observer 1	all pos.	all pos.	all pos.	all pos.	all neg.	all neg.	all neg.	all neg.
Observer 2	all pos.	all pos.	all pos.	all pos.	all neg.	all neg.	all neg.	all neg.
Observer 3	all pos.	all pos.	all pos.	all pos.	all neg.	all neg.	all neg.	all neg.

**Tab. 2: Statistical parameters of colors of pads from patients treated with A, R, D and of control groups, results of 1\*10<sup>4</sup> test strips, 2\* not analyzed.**

Parameter	Edoxaban	Dabigatran	Apixaban	Rivaroxaban
Mean	1.0	1.0	1.0	1.0
SD	1.0	1.0	1.0	1.0
CV	1.0	1.0	1.0	1.0
N	29	30	30	30

**Tab. 3: LC-MS/MS analysis of urine samples of 2 control patients (2 patients tested right).**

Ranges of concentration were: 100 to 6.60 µg/ml (A), 100 to 1.00 µg/ml (R) and 1.00 to 15.99 µg/ml (D).

Parameter	Edoxaban	Dabigatran	Apixaban	Rivaroxaban
Mean (µg/L)	1420	1922	3658	167
SD	81.5	88.6	93.6	167
N	29	30	30	30

### Financial support / address

The scientific work was supported by Doaense GmbH and Rosny Foundation (photographs by LW). Prof. Dr. Job Harenberg, DOAENSE GmbH, Waldstr. 102, D-69123 Heidelberg, info@doaense.de, www.doaense.de

# Akzidenzdrucksachen bis DIN A3+

## Gestaltung und Produktion von versch. Akzidenzdrucksachen

**When every minute counts ...**

... fast DOAC testing matters.

**DOAENSENSE**

Symposium XXIV<sup>th</sup> ISTH Congress  
Wed., July 12<sup>th</sup> 1:15 pm to 2:30 pm

**Management of Direct Oral Anticoagulants—challenges and perspectives**

Chairs: Rupert Bauersachs, Germany  
Eline Hylek, USA

1:15 pm **Introduction**  
Eline Hylek, USA

1:20 pm **Management of oral anticoagulants: decision making processes**  
Jeff Wells, Canada

1:35 pm **A need to test for DOACs in emergencies?**  
Wolfgang Korte, Switzerland

1:50 pm **Pros and Cons of DOAC tests in whole blood, plasma, and urine**  
Job Harenberg, Germany

2:05 pm **Do we need testing for DOACs in elective medical situations?**  
Jan Beyer-Westendorf, Germany

2:20 pm **General discussion**  
Rupert Bauersachs, Germany

Learn more about us  
**Booth # 41**  
Symposium  
Wed., July 12<sup>th</sup>  
Room HELSINKI

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info@doasense.de  
www.doasense.de

Flyer DIN A5, 2-stg.

A new generation of DOAC testing

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Notizblocks DIN A5

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Visitenkarten, 1-stg.

**DOAENSENSE**

**DOAENSENSE – Direct Oral Anticoagulant SENSing**

DOAENSENSE is an in vitro diagnostics company whose experts have more than 35 years experience in coagulation.

Our exclusive patent protected technology will change the way of testing for direct oral anticoagulants (DOACs), serving a so far unmet clinical need.

It is our objective to change the landscape of DOAC testing, that has long been limited to blood-sampling approaches with all their potential limitations.

**When every minute counts ...**

**DOAENSENSE**

New DOAC point of care testing: fast, reliable results with just a few drops of urine – no blood needed!<sup>b,c</sup>

DOACs are excreted to a large extent into urine by glomerular filtration and can be determined in urine.<sup>a,d</sup>

- easy to use
- easy to interpret
- reproducible
- sensitive and specific<sup>b,c</sup>

Only one single test strip is necessary for reliable detection of the DOACs of the classes of direct thrombin inhibitors, of Factor Xa inhibitors as well as of creatinine to check renal function.

Pad 1: for determination of creatinine

Pad 3: for determination of direct Factor Xa inhibitor

Pad 2: without reagent (to check color of urine)

Pad 4: for determination of direct thrombin inhibitor

Examples for results of test strips from urine samples:

Pad 1: creatinine normal  
Pad 2: urine color normal  
Pad 3 and Pad 4: DOACs negative

Pad 1: creatinine low  
Pad 2: urine color normal  
Pad 3: Factor Xa inhibitor positive  
Pad 4: thrombin inhibitor negative

Pad 1: creatinine high  
Pad 2: urine color normal  
Pad 3: Factor Xa inhibitor negative  
Pad 4: thrombin inhibitor positive

**Typical indications for DOAC testing:**

- Ischemic / hemorrhagic stroke
- Major trauma
- Emergency procedures
- Spontaneous thrombotic and bleeding events
- Acute surgery or invasive interventions
- Situations without available medication history

**In all these situations, it is essential to be aware of the presence or absence of DOACs for further therapy planning.**

4-Seiter DIN A4

**DOAENSENSE**

Questionnaire for testing DOACs

Do you use Direct Oral Anticoagulants (DOACs) for your patients?  Yes  No

If yes: How many patients are you treating long term with DOACs?  
 < 5  < 10  < 20  < 30  > 30

What are the reasons or indications for a patient for DOACs? *(multiple answers possible)*

Minor bleeding event  Emergency patient with an unknown history of medication

Major bleeding event  Stroke / IAB-Patient with an unknown history of medication

Therapy/compliance monitoring  Exclusion of overdose in renal insufficiency / kidney failure

Which methods do you currently use for testing on DOACs? *(multiple answers possible)*

No testing  aPTT  PT / INR  ECT  Factor Xa determination

How long does it take you to get the results of such a test? \_\_\_\_\_ min.

Would you like to have a Point-of-Care-Test for testing for DOACs available?  
 Yes  No  Not sure

Would you think that a sensitive, specific and rapid test for DOACs using test strips with urine could be a valuable tool for further medical decision making?  
 Yes  No  Not sure

If such a rapid test would be available in your country, please estimate for how many of your patients would you implement such a test within one year?  
 < 5  < 10  < 20  < 30  > 30

How much may such a Point-of-Care-Test cost, so that you would use it regularly?  
 €  4-5 \$

What do you specialize in? \_\_\_\_\_

Where do you work?  
 in a hospital  in a practice / own practice

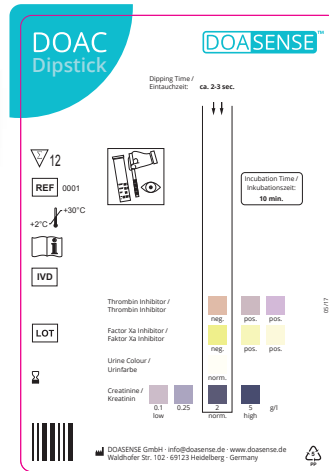
In which country do you work? \_\_\_\_\_

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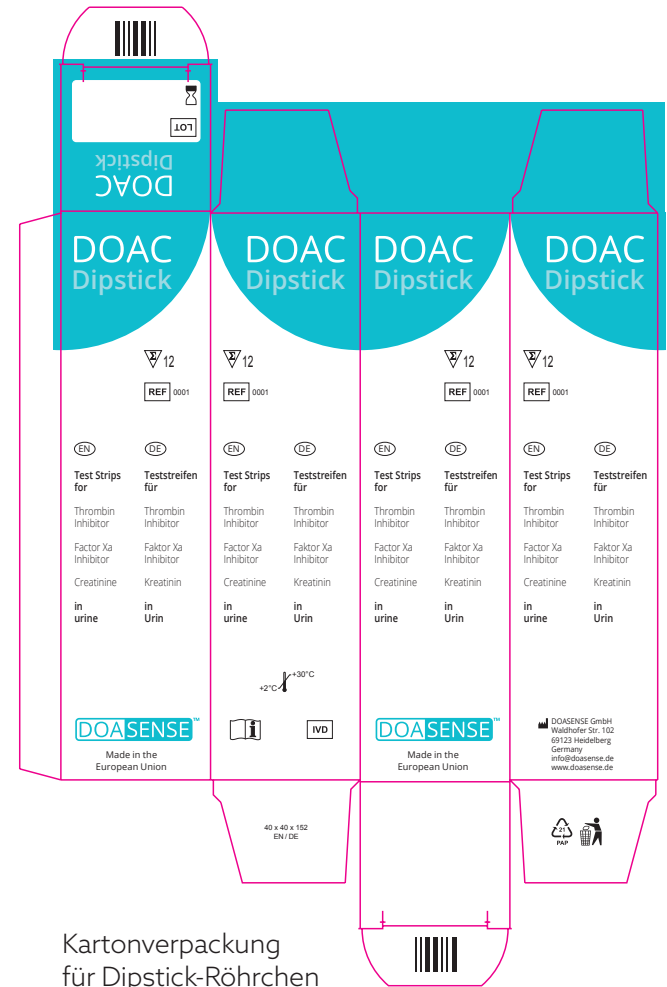
Fragebogen DIN A4, 1-stg.

# Musterverpackungen

## Gestaltung und Produktion von Musterverpackungen in Kleinauflage



DOAC Dipstick Etiketten,  
Format 122 x 85 mm



Kartonverpackung  
für Dipstick-Röhrchen



## Gestaltung und Programmierung einer Teaser-Rundmail an über 4.000 registrierte Teilnehmer kurz vor Messebeginn

- nahezu zeitgleicher, zentral gesteuerter Versand an über 4.000 E-Mail-Adressen über unseren Mail-Server
- Absendername, Betreffzeile, Absender- und Antwort-Adresse sowie die Bounce-Adresse (z.B. für nicht zustellbare E-Mails) unabhängig von einander frei wählbar
- E-Mail-Adressen der anderen Empfänger nicht sichtbar
- Plattformübergreifende HTML-Programmierung (responsive Design)
- personalisierte Ansprache
- geblockte Inhalte, wie Bilder, können über einen Link auf der DOASENSE-Website geladen und angesehen werden.

