

# Comparison of visual interpretation of the DOAC Dipstick test with a reader system for rapid and accurate detection of direct oral anticoagulants in neurology and cardiology – interim data from a prospective consecutive comparative study

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**INTRODUCTION** Direct oral anticoagulants (DOACs) are detected in patient urine samples by DOAC Dipstick test based on color changes in pads that contain specific chemical components. However, identification of these color changes may vary between observers and the test instructions may be difficult to follow in emergency situations.

**AIM** The objective of this ongoing study is to examine whether DOAC Dipstick results can be used to exclude the presence of clinically relevant concentrations of dabigatran, rivaroxaban and apixaban in patients admitted to a neurology and cardiology department for elective or emergency interventions.

## METHOD

In this interim analysis, we compared the inter-observer variability of DOAC Dipstick results obtained by medical personnel with those obtained by a semi-automatic reader.

This single center study will include between 120 and 180 patients with neurologic and cardiovascular diseases treated with rivaroxaban, apixaban and dabigatran who are admitted to Sestre Milosrdnice University Hospital Center in Zagreb.

Factor Xa and thrombin inhibitor pads of the DOAC Dipstick were incubated in patient urine samples and evaluated visually by two independent observers and by a DOASENSE Reader.

Here, we report interim descriptive results on variability of two observer and as compared to DOASENSE Reader results.

We will compare plasma DOAC concentrations with DOAC Dipstick results after termination of the study.

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## RESULTS

As of mid-February 2021, 45 patients were included into the project (rivaroxaban n=20, apixaban n=9, dabigatran n=10, and 6 patients in whom rivaroxaban was switched to dabigatran due decision of the treating physician).

The results of these 6 patients appear twice, once for DXI and DTI , respectively, to a total of 51 analyses.

So far, discordances of adjudication of colours for absence or presence of DXI and DTI on factor Xa and thrombin inhibitor pads of DOAC Dipstick were not observed between observers and compared to the results of DOASENSE Reader.

The Kappa Index (agreement between visual and Reader results) for DXI (Table 1) and DTI pad (Table2) is at present 1.0

## CONCLUSIONS

These interim data suggest low inter-observer variability of visual evaluation of DOAC





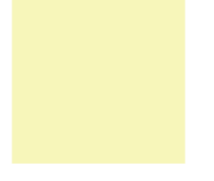
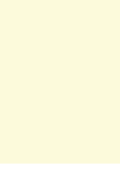




Dipstick colors for presence or absence of

DOACs and indicate a very high agreement

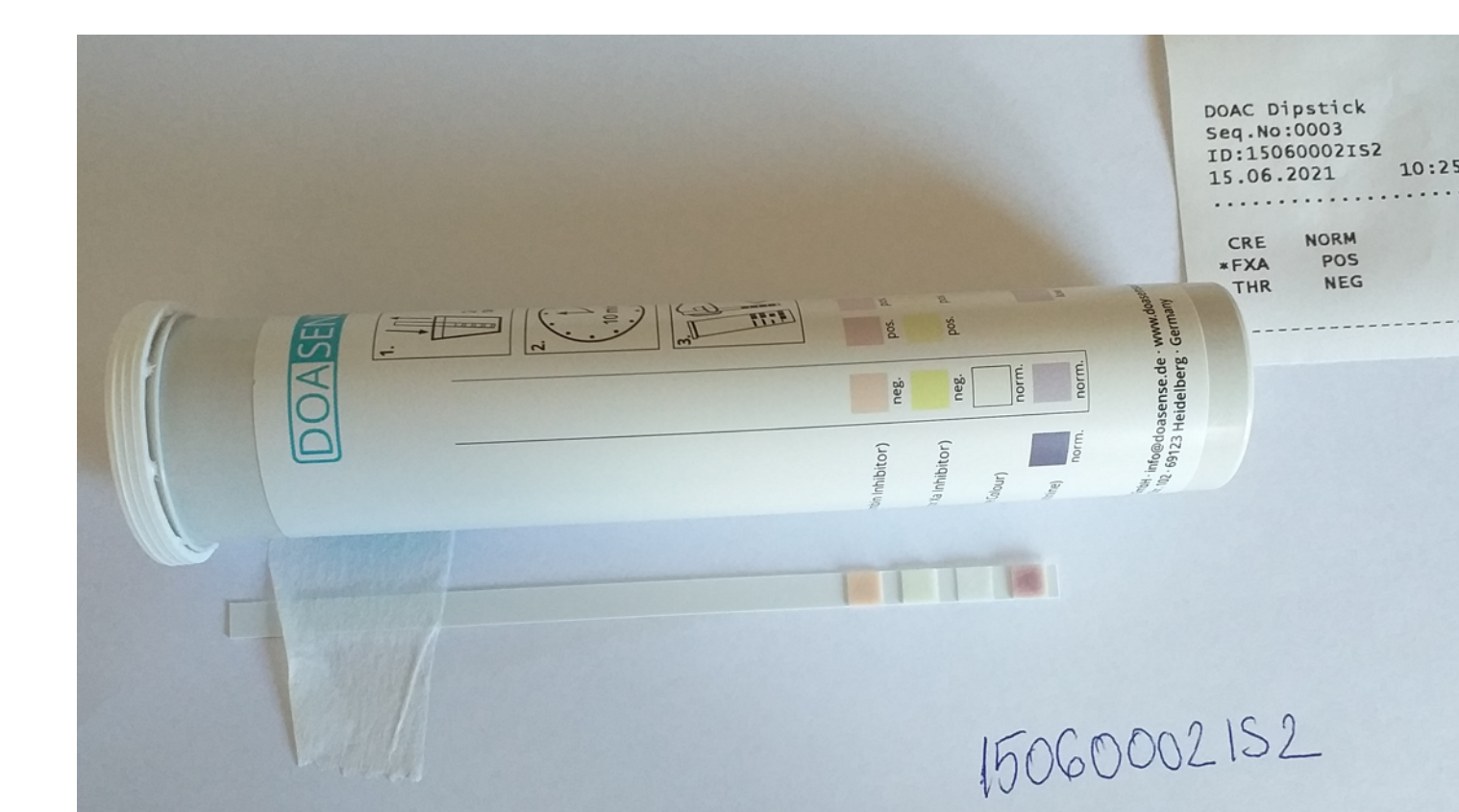
with results of DOASENSE Reader.

## RESULTS

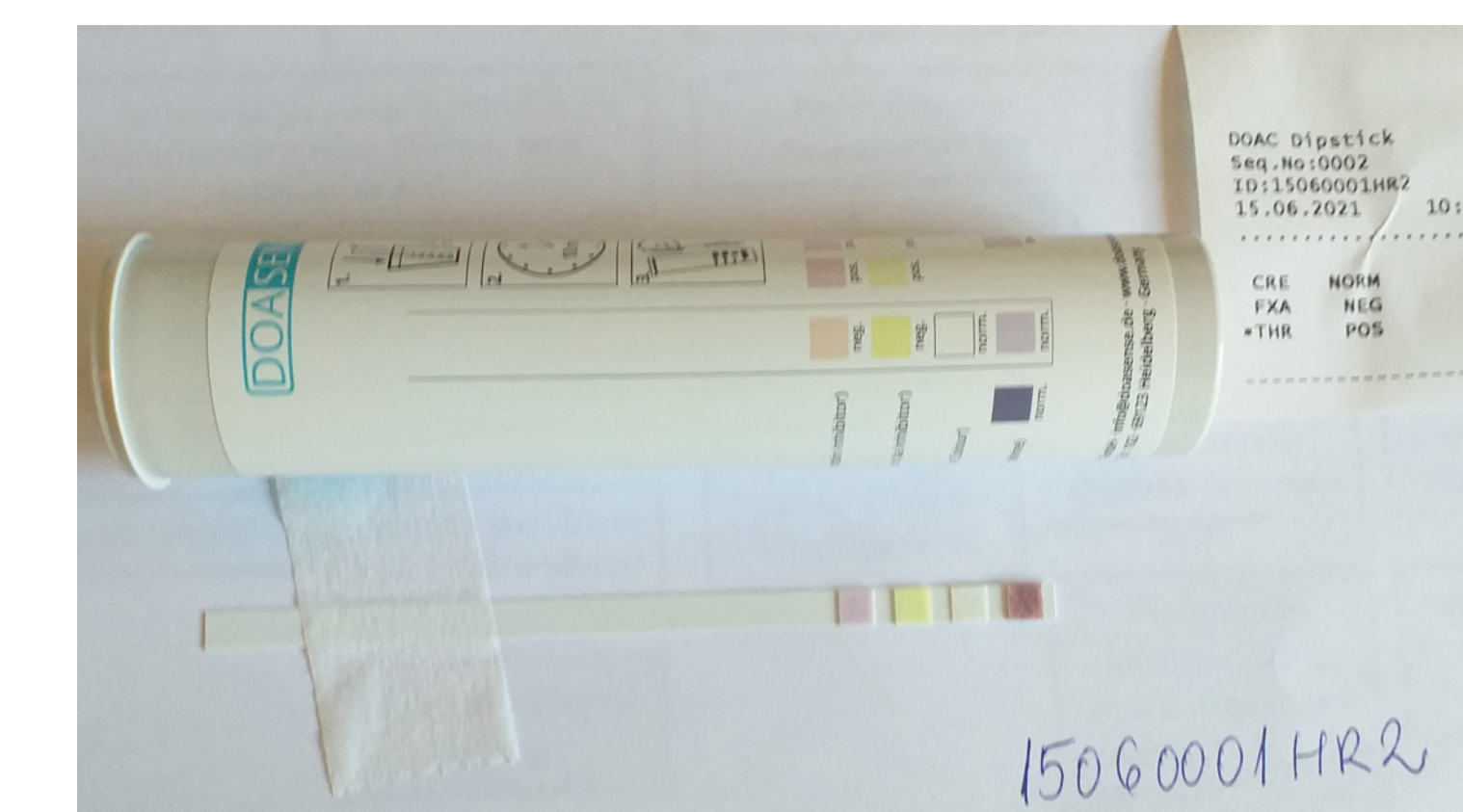
Figure: Colour label for DOAC Dipstick

Thrombin Inhibitor / Thrombin Inhibitor			
	neg.	pos.	pos.
Factor Xa Inhibitor / Faktor Xa Inhibitor			
	neg.	pos.	pos.
Urine Colour / Urinfarbe			
	norm.		
Creatinine / Kreatinin			
	norm.	norm.	low

Examples of digital photographs of patient's urine samples containing rivaroxaban (upper) and



dabigatran (lower) and



printouts of results by DOASENSE Reader

Table 1: paired results for DXI of visual vs reader analysis (preliminary)

	DXI	visual		
Reader		pos	neg	sum
pos		34	0	34
neg		0	17	17
sum		34	17	51

Table 2: paired results for DTI of visual vs reader analysis (preliminary)

	DTI	visual		
Reader		pos	neg	sum
pos		16	0	16
neg		0	35	17
sum		16	35	51

## AUDIO



## CONFLICT OF INTEREST

SM, DDB, IX, SSG, ALH, PV: none,  
JH: founder and managing director DOASENSE GmbH

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