Do not use expired devices.

**Warning and Precautions**

The DOAC Dipstick has four different test pads used for analysis as follows:

- **Pad 1 for colour determination of creatinine (Creatinine):**
  - The colour of pad 1 is darker than the colour marked "norm." on the tube label → high creatinine does not affect DOAC excretion into the urine sample.
  - The colour of pad 1 is "pos." or "neg." than the respective colour marked on the tube label → direct oral Factor Xa inhibitor is present in urine.

- **Pad 2 for determination of urine colour:**
  - The colour of the pad 2 is as white as the respective colour marked "norm." on the tube label → the results of pad 1, 3 and 4 are valid.
  - The colour of pad 2 is darker than the colour painted on the tube label → colours of pad 1, pad 3 and pad 4 may be distorted.

- **Pad 3 for determination of direct oral Factor Xa inhibitor:**
  - The colour of pad 3 is ochre as the respective colour marked "pos." on the tube label → direct oral Factor Xa Inhibitor is present in urine.
  - The colour of pad 3 is as white as the respective colour marked "neg." on the tube label → direct oral Factor Xa Inhibitor is absent in urine sample.

- **Pad 4 for determination of direct oral Thrombin inhibitor:**
  - The colour of pad 4 is rose as the respective colour marked "pos." on the tube label → direct oral Thrombin inhibitor is present in urine.
  - The colour of pad 4 is as white as the respective colour marked "neg." on the tube label → direct oral Thrombin inhibitor is absent in urine sample.

**Procedure Notes Before Performing the Test**

1. Immerse the test strip for 2 to 3 seconds into the urine sample so that all test pads are completely covered by the urine.

2. After removing the test strip from the urine, some liquid may be attached at the borders or edges of the test strip. Wipe off the excess urine on a tissue to avoid runoff. The test pads should not be touched.

3. Let the test strip sit for 1 minute and the urine sample in the test tube. Then remove the lid, and wait for 10 minutes (incubation time) Use a timer to check the time.

4. After 10 minutes incubation time immediately compare the test pads by naked eye to the corresponding colour scales on the label of the test container. Refer to the next section regarding the visual determination of the colours.

**Visual Determination and Evaluation of the Colours**

- Colours must be compared to colours of the colour scale printed on the label of the container by naked eye.

**Assay Procedure - Use of Test Strip**

1. After first opening the tube, the DOAC Dipsticks remaining in the tube can be used for a maximum of 3 months. Do not use any DOAC Dipstick beyond this period.

2. DOAC Dipsticks may be stored in the refrigerator for 12 months. Recommended storage temperature is between +2 °C and +30 °C. Do not freeze DOAC Dipsticks.

3. DOAC Dipsticks must not be allowed to dry out. Small amounts of water on the test strips will not affect the test results.

4. After first opening the tube, the DOAC Dipsticks remaining in the tube can be used for a maximum of 3 months. Do not use any DOAC Dipstick beyond this period.

**Performance Characteristics**

The new Doac Dipstick exhibits a specific and rapid detection of direct oral anticoagulants (DOACs: Dabigatran, Apixaban, Edoxaban and Rivaroxaban) in human urine by visual identification of colours. The DOAC Dipstick is intended for qualitative detection of the absence or presence of direct oral anticoagulants (DOACs: Dabigatran, Apixaban, Edoxaban and Rivaroxaban) in human urine by visual identification of colours. The DOAC Dipstick is intended for qualitative detection of the absence or presence of direct oral anticoagulants (DOACs: Dabigatran, Apixaban, Edoxaban and Rivaroxaban) in human urine by visual identification of colours.

**References**


**Symbols used**

- **Lot number**
- **Catalogue number**
- **Manufacturer**
- **Storage temperature**
- **Expiry date**
- **In vitro diagnostic device**

**Contact information for viva tests**

DOASENSE GmbH, Winterthurerstrasse 112, 60221 Heidelberg, Germany
Email: info@doasense.de, www.doasense.de

**Limitations**

The test results are qualitative. No quantitative interpretation should be made based on the test results. The results always are interpreted and evaluated in connection with other clinical data by a physician before diagnosing. No treatment decisions should be made solely based on the outcome of a DOAC Dipstick analysis. Additional laboratory analyses (e.g. determination of blood coagulation parameters) may be required.

Persons with colour vision deficiencies or colour blindness must not perform the DOAC Dipstick test.

**Expected Values and Reference Range**

**Creatinine**

- Normal values are below 5 ng/ml (LC-MS/MS-method). Patients under DOAC treatment typically display values above 200 ng/ml.

**Performance Characteristics**

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