Do not use expired devices.

**Summary and Explanation**

The test does not give positive results of a DOAC in human urine related to the presence of direct oral anticoagulants (DOACs) in blood. DOACs are excreted rapidly into urine starting 1 to 2 hours after intake of the medication. A specific and rapid detection by visual identification of colours can be done in the presence of DOACs especially in emergency medicine. Medical decision making may be accelerated. Typical indications are patients with ischemic or haemorrhagic stroke with indication for fibrinolysis or administration of a specific agent, major trauma, emergency procedures, spontaneous intracranial and bleeding events during oral anticoagulant therapy, and situations without available medication history.

The kidney excretes creatinine and DOACs into urine. Their excretion decreases with impairment of renal function. Consequently, DOACs accumulate in blood with decrease of renal function. Therefore, the parameter of creatinine was included on the DOAC Dipstick. DOAC Dipstick is a qualitative test for detection if DOACs are present in urine. DOAC Dipstick has four different test pads used for analysis as follows:

<table>
<thead>
<tr>
<th>Test Pad</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pad 1</td>
<td>Creatinine</td>
</tr>
<tr>
<td>Pad 2</td>
<td>Thrombin</td>
</tr>
<tr>
<td>Pad 3</td>
<td>Factor Xa</td>
</tr>
<tr>
<td>Pad 4</td>
<td>Thrombin Xa Inhibitor</td>
</tr>
</tbody>
</table>

**Material Provided and Test**

- Test strips (12 strips per test strip container with printed colour scale and cap)
- Test strip container made of polypropylene for urine sample
- Timer
- Container made of polypropylene for urine sample
- Test strips
- Urine medium (Benedict-Behre reaction).

**Visual Determination and Interpretation of Colours of DOAC Dipstick**

Colours of test pads should be compared with the respective substrates. No interaction occurs between the components of pad 3 with pad 4 and vice versa.

**Recommendations**

No treatment decisions should be made solely based on the outcome of a DOAC Dipstick analysis. Additional laboratory analysis may be required.

**Limitations**

The test results are qualitative. No quantitative interpretation should be made based on the test results.

The results always must be interpreted in conjunction with other clinical data by a physician before diagnosis. A second independent diagnostic test should be made based on the outcome of the DOAC Dipstick Analysis. Laboratory additional analysis (e.g. determination of blood coagulation parameters) may be required.

Recently voided urinary bladder may influence the detectable DOACs in the urine.

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

**Expected Value and Reference Range**

- Creatinine: Reference Range: 0.25 - 3.30 g/l (22 - 260 mmol/l) (Ref.: Nadler).

**Performance Characteristics**

The visual analyses of the colours of the DOAC Dipstick corresponds to results "negatives" and "positives". The cut-off value of Apixaban, Edoxaban, and Rivaroxaban is 0.5 ng/ml. The cut-off value for Dabigatran is 50 ng/ml. The cut-off values are given in urine spiked with concentrations of DOACs ranging from 0 to 1500 ng/ml. Using urine samples of patients treated with Apixaban, Edoxaban, and Rivaroxaban, a normal blood level of DOACs was obtained. Concentrations of DOACs in urine is used here higher than the lower volume of urine compared to the volume of distribution of DOACs in blood and urine samples were analyzed by LC-MS/MS-method. In patients not treated with DOACs and typically above 200 ng/ml DOACs during treatment and 12 or 24 hours after intake of medication (mean values 5-600 ng/ml Dabigatran, 2,700 ng/ml Rivaroxaban, 1,800 ng/ml Apixaban). (Ref.: Schreiner).

**Storage Conditions**

Starting at 3 months storage temperature the concentration of direct oral anticoagulants in the urine is declining. The test has to be performed between -20 °C and +30 °C. DOAC Dipstick is stored at 15°C to 25°C. DOAC Dipstick should be stored in a fridge at 15°C to 25°C for at least 3 months. Do not use any DOAC Dipsticks remaining in the tube after 3 months after last opening.

**References**


**SPECIALS**

- CE Mark, Device class I
- Lot number printed on each test strip container
- Expiry date
- RH: 0% ± 5%
- Test strips are stable at room temperature up to 2 years.
- Shelf life can be extended with refrigeration.

**Contact**

DOACSENSE GmbH, Weihrather Str. 102, 59123 Hedingbaum, Germany.
Email: info@doasense.de, www.doasense.de.