

DOASENSE Control Urines



REF 0003



Reference substances to be used with DOAC Dipstick (item no. 0001) and DOASENSE Reader (item no. 0002).

Intended Use

The DOASENSE Control Urines are reference substances for use with the DOAC Dipstick and the DOASENSE Reader. With these reference substances, you can test the functionality and quality of the DOAC Dipstick in vitro diagnostic medical device and the associated DOASENSE Reader. The DOASENSE Control Urines are only intended for use with the DOAC Dipstick and the DOASENSE Reader and are for professional use only.

Quality Control

To ensure the DOAC Dipstick and the DOASENSE Reader produce accurate results, their performance is confirmed by a test using the DOASENSE Control Urines (reference substances), which have known concentrations. DOASENSE recommends to test each new batch (i.e. units from one specific lot number) of DOAC Dipstick used at least once with the two Control Urines (Positive and Negative control urine). The DOASENSE Control Urines may be used more frequently, according to the individual requirements of the user.

Specification

Both types of DOASENSE Control Urines ("Positive" and "Negative") are available as a synthetic liquid. The reference substances contain a defined concentration of the direct oral anticoagulants (DOAC) rivaroxaban for factor Xa inhibitors, dabigatran for thrombin inhibitors and/or a defined concentration of creatinine. DOASENSE Control Urines are designed for direct use (ready for use). These reference substances must be treated in the same manner as patient samples and used according to the instructions for the DOAC Dipstick and DOASENSE Reader.

Contents of the DOASENSE Control Urines

Packaging of the control urines: 1
5 ml "Negative" reference substance in a glass vial with screw cap: 1
5 ml "Positive" reference substance in a glass vial with screw cap: 1
Instructions for use: 1

Materials Required, but not Provided

DOAC Dipstick
DOASENSE Reader, if needed
Timer, such as a stopwatch
Suction paper: absorbs excess control urine

Composition of DOASENSE Control Urines

- DOASENSE Control Urines are manufactured synthetically and do not contain any human urine. The reference substances contain preservatives to ensure the solution's stability and to minimize the risk of microbiological growth.
- The "Positive" reference substance for performing a positive DOAC control test contains rivaroxaban and dabigatran and a low concentration of creatinine.
- The "Negative" reference substance for performing a negative DOAC control test contains a normal creatinine concentration, but no rivaroxaban and dabigatran

Application Principle of DOASENSE Control Urines

The control urines are used with DOAC Dipsticks. DOAC Dipsticks each contain one pad to test for the presence of factor Xa inhibitors (apixaban, edoxaban, rivaroxaban), thrombin inhibitors (dabigatran) and creatinine as well as to assess the colour of urine.

The "Positive" DOASENSE Control Urine is used to test the pad colours on the test strip indicating a "positive" result (DOACs present in the urine) as well as a low creatinine concentration and a normal urine colour.

The "Negative" DOASENSE Control Urine is used to test the pad colours on the test strip indicating a "negative" result (no DOACs in the urine) as well as a normal creatinine concentration and a normal urine colour.

Rivaroxaban and dabigatran react specifically with the reagents on the factor Xa and thrombin inhibitor test pads, respectively. Neither DOACs will react with the test pad of the other DOAC. Therefore, both DOACs can exist in one solution.

Test Procedure

- Take the control urines from the refrigerator and let them adapt to ambient temperature (+20±5 °C) for approx. 10 to 15 minutes.
- Shake the control urines slightly.
- Note the date the respective control urine was first opened on the glass vial label.
- Open the screw cap carefully without tilting or holding the vial at an angle (liquid may leak).
- Dip the DOAC Dipstick into the vial for 2 to 3 seconds.
- When taking out the DOAC Dipstick, draw its edge over the vial edge to remove excess control urine.
- Wipe off excess liquid on the DOAC Dipstick with suction paper.
- Close the control urine vial tightly.
- After 10 minutes incubation time, the DOAC Dipsticks are evaluated either visually or with the DOASENSE Reader in accordance with the instructions for use of these products.
- Compare the obtained results with the results in the table (see "Evaluation").
- Put the control urines back into the refrigerator and store them at +2 to +8 °C.

Evaluation

The DOAC Dipstick instructions for use describe how to visually evaluate the colours of the DOAC Dipstick test pads. How to evaluate the DOAC Dipstick colours using the DOASENSE Reader is described in the instructions for use of the DOASENSE Reader. Human urine is evaluated in the same way as the artificial DOASENSE Control Urines. The expected results can be found in the table:

Control Urine	„Negative“	„Positive“
Test Pad	Result	
Creatinine	normal	low
Urine colour*)	normal	normal
Factor Xa inhibitor	negative	positive
Thrombin inhibitor	negative	positive

*) only for visual evaluation

• Visual evaluation of the DOAC Dipstick test pads or evaluation using the DOASENSE Reader **correspond** to the results in the table → DOAC Dipstick or DOASENSE Reader are **functional**.

• Visual evaluation of the DOAC Dipstick test pads or evaluation using the DOASENSE Reader **do not correspond** to the results in the table → DOAC Dipstick or DOASENSE Reader are **not functional**

Possible causes:

- Reference substances were mixed up
- Expiry date has passed
- DOAC Dipstick is not functional
- DOASENSE Reader is not functional

Procedure: Repeat the test with test strips from a new container.

- The result is not repeated → Dispose of the container with the test strips that produced the wrong result.
- The wrong result is repeated → Please contact the manufacturer and specify the lot number of the affected products.

Stability

Unopened DOASENSE Control Urines are stable up to the expiry date when stored between +2 and +8 °C. They must be protected against direct light and after first opening also against high humidity and contamination. After first opening, the DOASENSE Control Urines are stable between +2 and +8 °C for 3 months or for a total of 10 tests (whichever comes first).

Note the date the control urines were first opened on the label.

If stored incorrectly, the DOASENSE Control Urines may become non-functional.

Limitations

- This product must not be used after the expiry date on the packaging has passed.
- This product must not be used after 3 months from the first opening or after 10 tests (whichever comes first).
- If there are signs of microbial contamination or the product shows any turbidity, dispose of the reagent.

Health and First Aid

Suitable only for in vitro diagnostics and for use with DOAC Dipstick or DOASENSE Reader.

To be used only by trained medical staff.

Follow good laboratory practice and safety guidelines. Wear lab coats, disposable gloves and protective glasses.

In case of accidental oral intake, wash out the mouth and drink approx. 0.5 l water. In the event of eye contact, immediately rinse the eye thoroughly with clean water. Wash wetted skin with warm water and soap. If the reagent is accidentally swallowed or comes into contact with the eyes, consult a physician.

Disposal

The DOASENSE Control Urines are not infectious, toxic or harmful to the environment. They must be disposed of according to internal regulations. Paper and other packaging material must be disposed of separately (paper, glass, plastics).

WI7.5-8-EN-Rev02 - Date of revision: 2020-10-05

SYMBOLS

Expiry Date

CE Mark - Device complies with the Directive 98/79/EC

Lot Number

Manufacturer

Content is sufficient for <n> tests

In Vitro Diagnostics

Catalogue Number

Storage Temperature

Consult Instructions for Use

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