Using test strips must be handled as hazardous waste according to national biohazard and safety guidelines or regulations. All reagents of the test kit have been sterilized. However, materials contaminated with human urine can be infectious. For this reason, used test strips should be treated as potential biohazards in use and for disposal. If used test strips are disposed of in the urine, the test pad shall be removed based on the outcome of a DOAC Dipstick analysis. Additional laboratory analyses (e.g. determination of blood coagulation parameters) may be required. In cases with colour vision deficiencies or colour blindness, medical personnel may perform the DOAC Dipstick test. A recently noted urinary bladder may impair the detectability of DOACs in the urine.

Expected Values and Interpretation

Creatinine – Reference Range: 0.25 – 3.0 g/l, (2.2 – 26.5 mmol/l) (Ref.: Needleman). DOACs – Normal values are table (LC-MS/MS method). Patients under DOAC treatment typically display values above 200 ng/ml (Ref.: Schen). Performance Characteristics

The visual analysis of the colours of the DOAC Dipstick corresponds to results “negative” and “positive”. The cut off value of Apixaban, Dabigatran, Edoxaban, and Rivaroxaban is 50 ng/ml for “negative” and 100 ng/ml for “positive”. The cut off values of Dabigatran for “negative” is 50 ng/ml and for “positive” is 200 ng/ml. The cut off values of Dalteparin for “negative” is 500 ng/ml and for “positive” is 1000 ng/ml. The ranges between the cut off values of the colours of the sample pad 2 and 3 are marked in orange and may be used for the direct oral thrombin and direct oral factor Xa inhibitor test. Data were obtained in artificial urine and normal human urine. The results were compared to concentrations of DOACs ranging from 100 to 1500 ng/ml. Urine samples were prepared by the addition of known concentrations of DOACs into urine. Concentrations of DOACs in urine are higher due to the lower volume of urine compared to the volume of distribution of DOACs in blood. The cut off value of Laxoxaban, (LC-MS/MS method) is not known to be used in diagnosing and typing of DOACs in urine and typically above 200 ng/ml. The cut off value of Ximelagatran is below 5 ng/ml (LC-MS/MS method). No treatment decisions should be made solely based on the outcome of a DOAC Dipstick analysis. Additional laboratory analysis (e.g. determination of blood coagulation parameters) may be required. In cases with colour vision deficiencies or colour blindness, medical personnel may perform the DOAC Dipstick test. A recently noted urinary bladder may impair the detectability of DOACs in the urine.

Storage Condition

The test strip container must be stored in a cold, dry location. Test strips can be stored at ambient temperature without adverse effect. The expiration date must be observed. Do not store in hot, humid environments. The product is not affected by light. The test strip container must be stored in a cold, dry location. Test strips can be stored at ambient temperature without adverse effect. The expiration date must be observed. Do not store in hot, humid environments. The product is not affected by light. DOAC Dipstick is not affected by light. The test strip container must be stored in a cold, dry location. Test strips can be stored at ambient temperature without adverse effect. The expiration date must be observed. Do not store in hot, humid environments. The product is not affected by light. The test strip container must be stored in a cold, dry location. Test strips can be stored at ambient temperature without adverse effect. The expiration date must be observed. Do not store in hot, humid environments. The product is not affected by light.

References


No information is reported in the literature on drug-drug and drug-food interactions – except the coloured compounds in urine described above. The number of interactions tends to be low to very few due to the high specificity of the enzymes with a low occurrence in oral anticoagulation and their high concentration in urine. High conc. of the test strip container with printed colour scale and cap: 1

Experimental Protocols

The kidney excretes creatinine and DOACs into urine. Their excretion decreases with impairment of renal function. Consequently, monitoring indication by a point of care test may support diagnosis of anticoagulant therapy with DOACs especially in emergencies. In emergency procedures, spon- thrombin inhibitors and bivalirudin are used to allow bypass surgery.

The release of the chromophore is negatively related to the amount of DOAC in urine. Colours for oral direct Factor Xa and Thrombin inhibitor.

This pad does not contain any necessary. Do not reuse the test components.

Principle of Tests

In urine with high buffering capacity false low reading may be obtained. With high concentrations of ketone bodies (>50 mmol/l) the colours of pad 3 and pad 4 may be distorted. The impact of the colour of the urine sample can be assessed by pad 2 (see above for interpretation).

Assay Procedure – Use of Test Strips:

Remove the test strips from the plastic bag and place on a flat surface, so that you can see the test pads, and wait for 10 minutes (incubation time of tests). Use a timer to control the time. 4. Do not use test strips with an expiry date that has already passed.

Syringes – When using syringes, be aware of the possibility that a person is treated with both types of DOACs. Coloured compounds in urine such as bilirubin, urobilinogen and blood (macrohaematuria) may modify the results of pad 1, pad 3 and pad 4. If the impact of the urine sample can be assessed by pad 2 (see above for interpretation).

Concentrations of DOACs in urine are higher due to the lower volume of urine compared to the volume of distribution of DOACs in blood. The cut off value of Laxoxaban, (LC-MS/MS method) = 10 ng/ml, Dalteparin (LC-MS/MS method) = 300 ng/ml, Dabigatran (LC-MS/MS method) = 100 ng/ml, Edoxaban (LC-MS/MS method) = 50 ng/ml, Ximelagatran (LC-MS/MS method) = 5 ng/ml. Other DOACs are excreted rapidly into urine starting 1 to 2 hours after intake of the medication. A specific and rapid detection method is needed to diagnose anticoagulant therapy with DOACs in emergencies. Medical decision-making may be accelerated. Typical indications are patients with ischemic or haemorrhagic stroke because it is unlikely that a person is treated with both types of DOACs. If creatinine is low in urine, false negative results of DOACs may be detected in urine samples using DOAC Dipstick. If contamination of clothing occurs: Rinse skin with water or shower. If skin irritation occurs: Consult a physician in all serious cases of health damage. In case of an eye irritation: Rinse eyes with plenty of water. If irritation continues: Consult a physician. If skin irritation occurs: Consult a physician. If skin irritation occurs: Consult a physician. If skin irritation occurs: Consult a physician. If skin irritation occurs: Consult a physician.

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