Instruction for use

QuickSens® D-Dimer

Quantitative rapid test for the determination of D-Dimer in whole blood or plasma
Reference no.: LF01005

Intended use

QuickSens® D-Dimer is an immuno-chromatographic test for the determination of the fibrin degradation product D-dimer. It is performed to rule out pulmonary embolism (PE), disseminated intravascular coagulopathy (DIC) or deep vein thrombosis (DVT). The test can be performed with whole blood or plasma.

Principle of the test

The test contains two different monoclonal antibodies that are specific for human D-dimer, one of which is labelled with gold. If the sample to be examined contains D-dimer, the antibodies will form a sandwich complex (anti-D-dimer antibody (gold-labelled) ↔ D-dimer ↔ anti-D-dimer-antibody) as follows. The sample fluid dissolves the gold-labelled anti-D-dimer antibody out of its matrix. If the sample contains D-dimer, it forms an intermediary complex with this antibody, which flows over the test strip. At the position marked "T" there is a second anti-D-dimer antibody, which forms a sandwich with this intermediary complex. A red/purple test line becomes visible. The color intensity corresponds to the concentration of D-dimer (D-DU) in the sample.
Excess gold-labelled antibodies bind non-specific to the control line ("C"), indicating that the test worked properly.
If the sample contains no D-dimer, no sandwich complex is formed and, as a consequence, no test line is visible. Nevertheless, a control line appears ("C") in all tests that worked properly.

Contents of package

25 disposable QuickSens® D-Dimer tests
1 instruction for use

Additional material required

- Equipment for blood withdrawal with heparin, citrat or EDTA as anticoagulant
- Timer
- Sterile lancets or finger prickers
- Laboratory pipette and pipette tips
- Optoelectronic reader QuickSens® Ω100

Precautions and hazards

1. For professional use only.
2. Prior to performing the test, carefully read the instruction for use and follow it exactly. Deviations from the test instructions described here can lead to incorrect results.
3. The test must reach room temperature prior to use.
4. Do not use the test beyond the expiry date.
5. Use the exact sample volume specified in the section "Specimen".
6. Do not use serum as a sample.
7. Avoid touching the test area and do not apply any liquid.
8. Do not press on the cassette while the test is running.
9. The test result is valid only when read 15 minutes after the sample has been applied.
10. The result of the rapid test should only be evaluated in context with other laboratory values and the patient's clinical status.
11. All patient samples should be considered to be potentially infectious.
12. Always wear disposable gloves.

Storage and stability

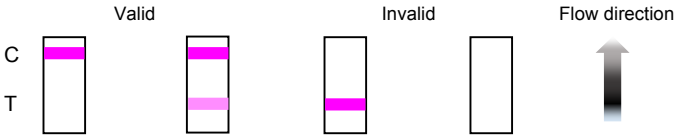
The QuickSens® D-Dimer test is stable until the expiry date printed on the package when stored between **+2°C and +8°C / 36°F and 46°F**. The test should be used on the same day after it has been removed from the sealed bag.

Procedure

Step 1 Open the sealed bag, remove the test and place it on a horizontal surface.
Step 2 The test must be at room temperature prior use.
Step 3 Label the test with the patient's identification.
Step 4 Apply **120 µl** whole blood or plasma in the sample reservoir ("S").
Step 5 Read out the test result **after 15 minutes** by using the reader QuickSens Ω100.

Interpretation of the test results

The red/purple control line ("C") indicates whether the test has worked properly. If the control line ("C") does not appear, the test has to be repeated with a new test. In this case please carefully read the instruction for use again and repeat the testing.



Note! If a result cannot be clearly interpreted, a rerun with a new test is necessary.

Valid test

The control line ("C") is visible. The D-dimer concentration is quantified by the reader QuickSens® Ω100.

Invalid test

No control line ("C") appears.

Functional control

The QuickSens® D-Dimer test contains an internal function control (control line "C"). This indicates that a sufficient sample volume has been applied and the chromatography worked properly.
Good Laboratory Practice recommends the use of positive and negative controls. The package does not contain control standards, but they are optionally available at 8sens.biognostic GmbH (Reference no.: LF01005-01).

Features and limitations

Measurement range: 28 – 3200 µg/l (D-DU)
Cut off: 66.4 µg/l (D-DU)

Sensitivity: 100 %
Specificity: 76 %
NPV: 100 %

A **negative test result** (< 66.4 µg/l) rules out the possibility of venous thrombosis, pulmonary embolism, or disseminated intravascular coagulopathy with high probability.

A **positive test result** (≥ 66.4 µg/l) indicates the need for further diagnostic testing (e.g. imaging).

Particularly in the elderly, during pregnancy, and in a variety of pathological conditions, fibrin formation may occur, which can lead to a "non-specific" elevation of the D-dimer antigen level. Additional causes for an elevated D-dimer antigen level include: vascular aneurysms, a portocaval shunt, haemangioma, liver cirrhosis, heparin-induced thrombocytopenia (HIT-II), malignant tumors, vascular damage (e.g. post-surgery), wounds, haematomas, sepsis, pneumonia, erysipelas, abscesses, osteomyelitis, coronary heart diseases, arteriosclerosis, atrial fibrillation, and fibrinolytic therapy (within the past 7 days).

Accuracy

The QuickSens® D-Dimer test fulfills the requirements of the EU Directive (IVDD). A comparison of 175 D-dimer measurements on the QuickSens® D-Dimer test to the StagoSTA Liatest® D-Dimer method yielded the following statistics (Passing-Bablok regression): slope: 1.045 and intercept:-87.09.

Precision

The inter-batch test showed that samples were properly identified in > 99 % of the cases.
The intra-batch test showed that samples were properly identified in > 99 % of the cases.

Sample material

The test works with both capillary and venous whole blood. It may be used with or without added anticoagulants (heparin, citrate or EDTA). The test also works with plasma. Do not use serum as a sample.
Sample volume: 120 µl
Sample shelf life: Blood samples should be used within 8 hours after collection, and may not be frozen. Do not repeatedly freeze and thaw plasma samples.

Disposal

All clinical samples must be disposed of in accordance to the appropriate regulations, respectively after being autoclaved, all samples and used tests may be disposed of in the domestic waste.

Key to symbols

	Consult instruction for use		Temperature limits (storage)
	For single use only	LOT	Batch no.
n	Sufficient for n tests		Expiry date YYYY-MM (EXP)
REF	Reference no.		Manufacturer
IVD	In-vitro-diagnostic		

References

- G J Geersing, K J M Janssen, R Oudega, LBax, A W Hoes, J B Reitsma, K G M Moons. Excluding venous thromboembolism using point of care D-dimer tests in outpatients: a diagnostic meta-analysis. BMJ 2009; 339:b2990
- E F van der Velde, D B Toll, A J. ten Cate-Hoek, R. Oudega, H E J H Stoffers, P M Bossuyt, H R Büller, M H Prins, A W Hoes, K G M Moons, H C P van Weert. Comparingthe diagnostic performance of 2 clinical decision rules to rule out deep vein thrombosis in primary care patients. ANNFAMMED 2011, Vol. 9, No. 1

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