D-Dimer Rapid Test Kit (Colloidal Gold)

CE IVD

PRODUCT NAME
D-Dimer Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The D-Dimer Rapid Test is used for the qualitative detection of D-Dimer in human whole blood and plasma. The test is used as an aid in the assessment and evaluation of patients with suspected disseminated intravascular coa-gulation (DIC), deep vein thrombosis (DVT) and pulmonary embolism (PE).

INTRODUCTION
During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non crosslinked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-Dimer and are called crosslinked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-Dimer are a specific marker of fibrinolysis.
The detection limit of the D-Dimer Test is 500 ng/mL D-Dimer.

TEST PRINCIPLE
The D-Dimer Rapid Test (whole blood/ plasma) detects D-Dimer through visual interpretation of color development in the internal strip. Anti-D-Dimer antibodies are immobilized on the test region of the membrane, and anti-mouse antibodies are immobilized on the control region. During testing, the specimen reacts with anti-D-Dimer antibodies conjugated to colored particles and precoated onto the specimen pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient D-Dimer in the specimen, a colored band will form at the test region of the membrane.
The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indication that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS SUPPLIED
- D-Dimer tests, incl. disposable pipettes
- buffer
- package insert

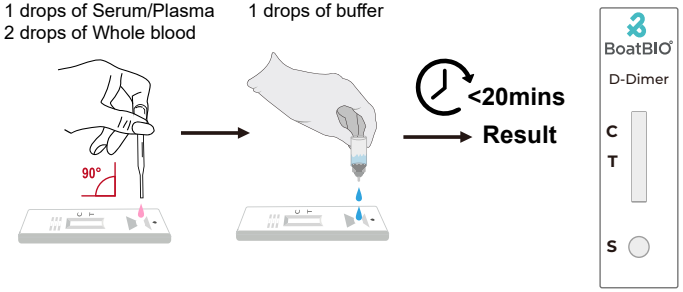
STORAGE AND STABILITY
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze!
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological conta-mination of dispensing equipments, containers or reagents can lead to false results.

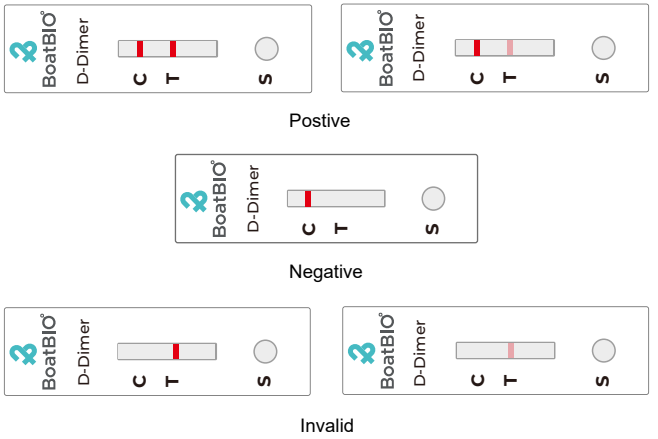
WARNINGS AND PRECAUTIONS
- This kit contains products of animal origin. Certified knowledge of the origin and/ or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g.do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of speci-mens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when speci-mens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

SPECIMEN COLLECTION AND PREPARATION
Specimen Collection
- The D-Dimer Rapid Test (whole blood/plasma) is intended for use with human whole blood or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Plasma should be separated as soon as possible to avoid hemolysis.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Specimen Transport and Storage
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8°C for up to 1 day. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be performed within 1 day of collection. Do not freeze whole blood specimens! Whole blood collected by fingerstick should be tested immediately.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

TEST PROCEDURE
Bring tests, buffer, specimens and/or controls to room temperature (15-30°C) prior to testing.
1. Remove a test cassette from the foil pouch and use it as soon as possible. The best results will be obtained if the test is performed immediately after opening the foil pouch. Label the test cassette with the patient's name or control identification.
2. Place the test cassette on a clean and level surface.
3. a) For plasma specimens: Holding a pipette vertically, add 1 drop (approximately 25 µL) of the plasma specimen to the specimen well (S) of the test cassette.
b) For venipuncture whole blood specimens: Holding a pipette vertically, add 2 drops(approximately 50 µL) of the whole blood specimen to the specimen well (S) of the test cassette.
c) For fingerstick whole blood specimens: Position the patient's finger so that a drop of blood is exactly above the specimen well (S) of the test cassette. Allow 1 hanging drop of fingerstick whole blood (approximately 50 µL) to fall into the centre of the specimen well (S) of the test cassette.
4. Holding the buffer bottle vertically, add 1 drop of buffer to the specimen well (S) of the test cassette.
5. Start the timer.
6. Wait for the coloured line(s) to appear. Read the test result after 10 minutes. Do not interpret the result after more than 20 minutes.





RESULT INTERPRETATION
Positive result
Two coloured lines appear on the membrane. One line appears in the control line region (C) and the other line appears in the test line region (T).
Note: The colour intensity in the test line region (T) may vary depending on the concentration of the analyte present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive. Note that this is a qualitative test only and it cannot determine the analyte concentration in the specimen.
Negative result
One coloured line appears in the control line region (C). No apparent coloured line appears in the test line region (T).
Invalid result
The control line (C) fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.
Note:
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL
- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
- The D-Dimer Rapid Test (whole blood/ plasma) is for professional in-vitro diagnostic use and should only be used for the qualitative detection of D-Dimer.
- Clinical diagnosis should not be based on the result of the D-Dimer rapid test only. The full clinical context of the patient should be included when making a diagnostic decision, taking into account the clinical signs and other relevant information such as the «Well's pre-test probability score» or equivalent.
- Negative D-Dimer results can occur very occasionally even in the presence of a DVT due to other factors including the age or position of a clot, heparin therapy and when the D-Dimer concentration is below the sensitivity of the test.

EXPECT VALUE
Elevated levels of D-Dimer are an indication of active fibrinolysis and have been shown in patients with disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT) and pulmonary embolism (PE). Elevated levels of D-Dimer have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, malignancy and in the elderly. D-Dimer levels also rise during normal pregnancy but very high levels are associated with complications.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

The detection limit of the D-Dimer Rapid Test is 500 ng/mL (fibrinogen equivalent units: FEU). No hook effect was observed when testing a specimen containing a D-Dimer concentration as high as 50 µg/mL.

Diagnostic sensitivity and specificity

A clinical study was performed on 149 negative plasma specimens (EIA confirmed, Roche Cobas c701) and 153 positive plasma specimens (EIA confirmed). The results are presented in the following table:

Method		EIA		Total Results
D-Dimer Rapid Test	Results	Positive	Negative	
	Positive	151	16	167
	Negative	2	133	135
Total Results		153	149	302

Relative sensitivity: 151/(151+2) = 98.7% (96.91% - 100%)*
Relative specificity: 133/(133+16) = 89.3% (84.34% - 94.26%)*
Overall agreement: (151+133)/(151+2+133+16) = 94.0% (91.36% - 96.72%)*
*95% Confidence interval

Cross-reactivity

1 mg/mL fibrinogen, 25 µg/mL fragment D and 25 µg/mL fragment E do not cross-react with the D-Dimer Rapid Test. Elevated levels of rheumatoid factors (RF) or heterophile antibodies might interfere with test results.

Interfering substances

Negative and positive specimens spiked with the following potentially interfering substances were evaluated in triplicates using the D-Dimer Rapid Test.

Analyte	Concentration	Analyte	Concentration
Human albumin	110 mg/mL	Hydrochlorothi azide	50 µg/mL
Acetaminophen	50 µg/mL	D,L-Tyrosine	50 µg/mL
Acetylsalicylic acid	50 µg/mL	Labetalol	50 µg/mL
Ascorbic acid	50 µg/mL	Oxazepam	50 µg/mL
Atenolol	50 µg/mL	Phenobarbital	50 µg/mL
Atorvastatin calcium	50 µg/mL	Quinine	50 µg/mL
Anisodamine	50 µg/mL	Triglycerides	15 mg/mL
Bilirubin	6 mg/mL	Trimethoprim	50 µg/mL
Chloramphenicol	50 µg/mL	Verapamil	50 µg/mL
Chlordiazepoxide	50 µg/mL	Felodipine	50 µg/mL
Cholesterol	5 mg/mL	Nifedipine	50 µg/mL
Caffeine	50 µg/mL	Bisoprolol fumarate	50 µg/mL
Captopril	50 µg/mL	Ramipril	50 µg/mL
Cilazapril	50 µg/mL	Metoprolol tartrate	50 µg/mL
Diclofenac	50 µg/mL	Moricizine hydrochloride	50 µg/mL
Digoxin	50 µg/mL	Pentoxifylline	50 µg/mL
Erythromycin	50 µg/mL	Flunarizine hydrochloride	50 µg/mL
Isosorbide mononitrate	50 µg/mL	Haemoglobin	10 mg/mL
Furosemide	50 µg/mL		

None of the substances interfered with the assay at the concentrations tested.

Precision

Repeatability and reproducibility

Repeatability was established by testing 10 replicates of 3 specimens (0 ng/mL, 500 ng/mL and 2000 ng/mL D-Dimer) with each of 3 independent D-Dimer Rapid Test lots.
Reproducibility was established by testing triplicates of 3 specimens (0 ng/mL, 500 ng/mL and 2000 ng/mL D-Dimer) with 3 independent D-Dimer Rapid Test lots.
The D-Dimer Rapid Test demonstrated acceptable repeatability and reproducibility. The negative and positive values were correctly identified >99% of the time.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	**Use-by date**		**Consult instructions for use**
	**Batch code**		**In vitro diagnostic medical device**
	**Temperature limit**		**Manufacturer**
	**Please don't reuse it**		**Keep away from sunlight**
	**Don't use the product when the package is damaged**		**Keep dry**
	**Date of manufacture**		**Tests per kit**
	**CE Mark**		**Biological Risks**
	**Authorized representative in the European Community**		

BASIC INFORMATION

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