Cleartest® D-dimer

Test for the qualitative detection of D-dimer in whole blood and plasma.

A rapid test for the qualitative detection of D-dimer in whole blood and plasma.

FOR PROFESSIONAL IN-VITRO DIAGNOSTIC USE ONLY.

INTENDED USE
The Cleartest® D-Dimer test is a immunological chromatographic test for the qualitative detection of D-Dimer in whole blood or plasma specimens to indicate coagulopathy and fibrinolytic activity. The test is intended to be used for the exclusion diagnostic of pulmonary embolisms, deep vein thrombosis and disseminated intravascular coagulation (DIC).

SUMMARY
During blood coagulation, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked 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-lasing 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 cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

PRINCIPLE
The Cleartest® D-Dimer test is intended for use in the detection of elevated D-Dimer in whole blood or plasma specimens. This information can be used by the physician to detect a thrombus and/or to exclude certain clinical conditions like pulmonary embolisms, deep vein thrombosis and disseminated intravascular coagulation (DIC) if a negative result is obtained. The Cleartest® D-Dimer test has been designed to detect the elevated D-Dimer concentrations through visual interpretation of colour development in the test device, which is an immunochromatographic immunocassay.

During the test the patient specimen is allowed to react with a coloured conjugate which was immobilized on the pad inside the test cassette. The mixture then migrates on the membrane chromatographically by capillary action.

When D-Dimer containing molecules are present in a sample, a colour line with a specific Marker of fibrinolysis. Therefore, fibrin derivates in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

MATERIALS PROVIDED
- Cleartest® D-Dimer test card
- Disposable droppers
- Buffer
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Specimen collection containers (for venipuncture whole blood)
- Timer
- Lancet (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

TEST PROCEDURE
- Allow the Cleartest® D-Dimer test to equilibrate to room temperature (15-30°C) prior to testing.
- Remove the Cleartest® D-Dimer test from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch. Place the test device on a clean and level surface.

Venipuncture Whole Blood
Hold the dropper vertically and transfer 1 drop of venipuncture whole blood (approximately 20 µL) to the specimen well of the test device.

Plasma
Hold the dropper vertically and transfer 10 µL of plasma with a micropipette (not included in test kit) to the specimen well of the Cleartest® D-Dimer test.

Immediately add 3 drops of buffer to the specimen well. Then start the timer.

Wait for the coloured line(s) to appear. Read results at 8 minutes. Do not interpret results after more than 9 minutes.

- Specimens showing evidence of clotting are not suitable for testing. Use only clear, non-hemolysed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood specimens may be stored refrigerated at 2-8°C for 24 hours. Plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- Specimens showing precipitate may yield inconsistent results and must be clarified prior to testing.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

STORAGE AND STABILITY
Store as packaged in the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

COLLECTION AND PREPARATION
- The Cleartest® D-Dimer test can be performed using whole blood and plasma.
- Use collection container treated with anticoagulants like heparin, EDTA or sodium citrate when collecting whole blood specimens.

Collecting Fingerstick Whole Blood specimens:
- Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertips of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using a capillary:
  - Touch the end of the capillary tube to the blood until filled to approximately 20 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test device.

To collect Venipuncture Whole Blood specimens:
- Collect anti-coagulated blood specimen (heparin, EDTA, sodium citrate) following standard laboratory procedures.
**INTERPRETATION OF RESULTS**

**Negative:**
One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T).

**Positive:**
Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

**Invalid:**
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test immediately and contact your local distributor.

**LIMITATIONS**
1. The Cleartest® D-Dimer test is for in vitro diagnostic use only. The test should be used for the detection of elevated D-Dimer levels in whole blood or plasma specimens only.
2. Very high concentrations of D-Dimer (>60 µg/ml) can lead to reduced test line intensity.

3. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. A low incidence of false results may occur.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity**
The Cleartest® D-Dimer test has correctly identified a panel of specimens and has been compared to a leading commercial D-Dimer rapid test. The result shows that the sensitivity of the Cleartest® D-Dimer test is 97%, and the specificity is 92%.

**Interfering Substances**
The Cleartest® D-Dimer test has been tested and no interference was observed in specimens containing 500 mg/ml triglyceride, 0.1 mg/mL bilirubin, 10 mg/mL haemoglobin (haemolyzed specimens), 1000 mIU/ml prostatic acid phosphatase, and 20 mg/ml albumin.

**SYMBOLS**

**MANUFACTURER**
Servoprex GmbH
Am Marienbusch 9
46485 Wesel
Germany

Tel: 0049 281 95 28 30
Fax: 0049 281 56071/72