Nano-Check™ D-Dimer Test

For in vitro Diagnostic Use

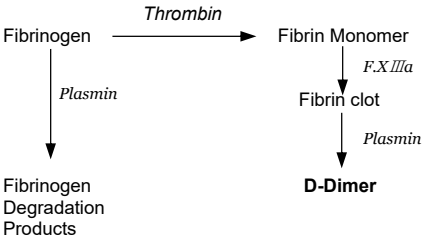
Immuno-chromatography assay for the detection of D-dimer in human whole blood and plasma specimens

1. INTENDED USE

Nano-Check™ D-Dimer Test is a rapid immuno-chromatography test for the evaluation of cross-linked fibrin degradation products containing D-Dimer in human whole blood and plasma specimens with Nano-Checker 710 Reader. The test is used as an aid in the diagnosis of Disseminated Intravascular Coagulation (DIC), or Venous Thromboembolism (VTE), which includes Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE).

2. SUMMARY AND EXPLANATION OF THE TEST

Blood coagulation is complete by the formation of insoluble fibrin clot through the polymerization of soluble fibrin monomer by factor XIIIa catalyzation.



The clotted fibrin is ultimately degraded via the fibrinolysis process. During the process, Plasmin cleaves cross linking bonds in fibrin clots and generates fibrin degradation products including cross linked dimer form of D-molecules. D-Dimer is a final product which is triggered by blood coagulation in the blood stream. Elevation of D-Dimer in the blood stream of patients with pulmonary embolism and deep venous thrombosis have been reported by Goldhaber.

3. PRINCIPLE

Nano-Check™ D-Dimer Test is membrane based immuno-chromatographic assay for the evaluation of D-Dimer in patient blood stream. The membrane strip contains a test line and a control line printed with fibrin degradation product (FDP) antibody and rabbit anti-goat IgG antibody. A dye pad containing colloidal gold particles coupled with D-Dimer specific monoclonal antibody is placed at the end of the membrane and covered with porous sample pad. When the specimen containing D-Dimer is applied to the sample pad through sample well in the plastic device, the D-Dimer molecules in the specimen bind to the D-Dimer specific antibody. These immune complexes move along the nitrocellulose membrane through the test lines and bind to anti FDP antibody immobilized on the test lines. If the concentration of D-Dimer in the specimen is above the detection limit level (300ng/ml), red lines appear at the corresponding test lines and the control line. If the concentration of D-Dimer in the sample is lower than the detection limit level, only the colored control line can be seen in the test window. This colored control band must always appear at the control line position (Con) for valid test results. A test result is not valid if the colored control line does not appear in the test window.

To measure the concentration of analyte, the tested device should be read by Nano-Checker 710 Reader. The reader can analyze color intensity of the test line and convert it to concentration of the analyte in the specimen by the predetermined equation.

4. REAGENTS AND MATERIALS

Provided

- 20 Test devices in a sealed aluminum pouch with desiccant
- 20 Disposable droppers
- 1 Bottle of developer
- Instructions for Use

Required but not provided

- Whole blood or Plasma Collection Container
- Positive and negative quality control materials
- Timer
- Nano-Checker 710 Reader
- Lancet and Alcohol Swap

5. STORAGE AND STABILITY

The test kit should be stored at 2°C - 30°C in the original sealed pouch for the duration of shelf life.

6. PRECAUTIONS

- For *in-vitro* diagnostic and professional use only.
- Handle all specimens as potentially infectious.
- Proper handling and disposal methods should be established.
- To avoid cross contamination, use a fresh transfer device for each clinical sample tested.
- Do not use test kit if the pouch is damaged or improperly sealed.
- Do not use test kit beyond expiration date.
- For validated result, only Developer solution provided with device should be used.

7. SPECIMEN COLLECTION AND PREPARATION

- The samples should be collected under standard laboratory conditions.
- Optimal results were obtained when patient samples were tested immediately after collection.
- Whole blood samples should be used within 4 hours after collection.
- Plasma samples may be refrigerated for 24 hours at 2-8°C. If testing cannot be performed within 24 hours, or for shipment of samples, freeze at -20°C or colder.
- Sodium azide can be added as a preservative up to 0.1% without affecting the test results.
- Refrigerated or frozen plasma specimen should reach room temperature and be homogeneous prior to testing
- Avoid using severely hemolyzed specimens, if a specimen hemolyzed severely, obtain a fresh specimen to be tested.

8. TEST PROCEDURE AND PROTOCOL

a) Collect specimen according to instructions in "Specimen Collection".

b) Test device and sample should be brought to room temperature prior to testing.

c) Remove the test device from the sealed pouch immediately before use. Label the device with patient or control identification.