MediRox

CE

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MRX D-Dimer Reagent Art. No: MRX147B

INTENDED USE

MRX147B is a micro-particle enhanced immunoassay for the quantitative determination of D-dimer in human citrated plasma. MRX147B is suitable for coagulation and clinical-laboratory instruments using turbidimetric detection in the 400-600 nm wavelength range.

FOR IN VITRO DIAGNOSTIC USE

BACKGROUND AND PRINCIPLE OF METHOD

Fibrin fragments containing D-dimer antigen is always present in plasma as a result of plasmin degradation of cross-linked fibrin. After an injury, or when suffering from conditions associated with increased hemostatic activity, there is an increase in plasma D-dimer concentration. The determination of D-dimer has become a prevalent aid in the diagnosis of thrombosis. Elevated levels of D-dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC)1-4. A negative D-dimer test result from a patient with a suspected thrombotic disorder has a high negative predictive value. MRX147B D-Dimer consists of sub-micron sized polystyrene particles coupled to monoclonal antibodies specific for D-dimer. When the reagent is exposed to a D-dimer containing plasma sample, the particles will agglutinate, giving rise to increased light-scattering. When exposed to the appropriate wavelength of light, the increase in measured turbidity, or light-scattering, is proportional to the amount of D-dimer in the sample.

PRODUCT DESCRIPTION

The D-dimer Kit contains:

- Latex Reagent: 5 x 6 mL polystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilizers and Sodium Azid (<0,1%) as preservatives.
- Reaction Buffer: 5 x 7 mL containing buffer and Sodium Azid (<0,1%) as preservatives.

PRECAUTIONS

Avoid contact with skin and eyes. Wear suitable clothing for protection.
The reagent contains Sodium Azide as preservative and should be disposed of in accordance with national and local regulations. Do not empty into drains. For more information see the Safety Data Sheet.

PREPARATION

- Latex reagent:
  Ready to use. As the micro-particles will settle during storage, swirl the vial gently a few times before each day it is used, to ensure a homogenous suspension. Do not shake.
- Reaction Buffer: The reagent is ready to use.

STORAGE CONDITIONS AND STABILITY

Unopened Latex reagent and Reaction Buffer are stable until the expiration date shown on the vials when stored at 2-8°C.
Opened Latex reagent and Reaction Buffer are stable for four weeks at 2-8°C and for two weeks at 8-25°.

SPECIMEN COLLECTION AND STORAGE

Venous blood is collected in 0,11 or 0,13 M trisodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio). The ratio is critical. If using commercial vacuum tubes, a full draw must be assured. Trauma or stasis during blood sampling should be avoided.. The presence of a clot in a specimen is a cause for rejection.
Refer to CLSI guideline H21-A5 for further instructions on specimen collection, handling and storage 9.
Plasma samples can be stored at room temperature (18-25°C) for up to 4 hours; refrigerated (2-8°C) for up to 4 hours; frozen at -20°C for up to 2 weeks or at -70°C for up to 6 months. Frozen samples should be thawed rapidly and tested immediately. If testing cannot be performed immediately, the sample may be kept refrigerated (2-8°C) for maximally 2 hours prior to testing. No contact with glass should occur.

PROCEDURE

Refer to appropriate operator's manual for each instrument and the instrument-specific MRX147B D-dimer application sheet.

Material required but not included in the kit:

- D-Dimer Calibration Plasma (MRX 144)
- Controls (GHI 167B/170/162/164)
- Owren Buffer (MRX150) or Saline

The user must run a complete standard curve for each new lot of reagent and if the control values are outside the assigned range.

QUALITY CONTROL

MediRox recommends the use of normal control plasma (GHI162/164) and abnormal control plasma (GHI167B/170) for reliable quality control of the performance and at a frequency in accordance with good laboratory practice.

LIMITATIONS AND INTERFERENCE

D-Dimer MRX147B is not affected by UF and LMW Heparin up to 100 U/mL, by Bilirubin up to 0,1 g/L, by Triglycerides up to 2,5 g/L and by Hemoglobin up to 4 g/L. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA). Such antibodies may cause over-estimation of D-dimer levels. The presence of rheumatoid arthritis factor may result in falsely elevated D-dimer values. Turbid or opalescent plasma may cause erratic results and should be interpreted with caution; dilute the sample and reassay.
The monoclonal antibody in MRX147B has been screened for its specificity against cross-linked fibrin degradation products. MRX17B D-dimer has more than 100-fold specificity for D-dimer (Fibrin or purified D-dimer), over Fibrinogen, Fibrinogen D or Fragment E.

EXPECTED RESULTS

The D-dimer results should be used together with other clinical and diagnostic information for forming a diagnosis. The normal level of D-dimer in the population is typically below 200 ng/mL4,5. However, as there is no internationally established standard for D-dimer, the concentration of D-dimer in any given specimen may differ when determined using D-dimer assays from different manufacturers. Thus, each laboratory should establish its own reference range and cut-off values. Elevated levels of D-dimer are found in patients with deep venous thrombosis (DVT), pulmonary embolism, disseminated intravascular coagulation and trauma6. D-Dimer levels increase during pregnancy7 and with age8. D-Dimer results can be reported in units of D-dimer (ng/mL) or in Fibrinogen Equivalent Units (FEU). 1 ng/mL D-Dimer is approx. 2 FEU.

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