MediRox

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Changes: Added information for Product description and Limitations and interferences about HBR in the Reaction Buffer. Updated text for Background and principle of method, for Preparation and for Stability. Material needed but not included: MRX184 instead of GHI150 recommended. Performance characteristics included.

MRX D-Dimer Reagent Art.No: MRX143

INTENDED USE

For the quantitative determination of the fibrin degradation product D-dimer in human citrated plasma. Suitable for photometric instruments in the 600-800 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. MRX143 D-Dimer consists of sub-micron sized polystyrene particles coupled to monoclonal antibodies specific for D-dimer. When the reagent is exposed to a plasma sample containing D-dimer, 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 4 mL polystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilizers and sodium azid (<0,1%)
- Reaction buffer: 5 x 7 mL containing buffer, HBR (Heterophilic Blocking Reagent) and sodium azid (<0,1%)

PRECAUTIONS

Avoid contact with skin and eyes. Wear suitable clothing for protection. The reagent contains sodium azid (less than 0,1%) to prevent microbial growth and should be disposed of in accordance with national and local regulations. Do not empty into drains. For more information see Material Safety Data Sheet.

PREPARATION

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

STORAGE CONDITIONS AND STABILITY

Latex Reagent: Unopened reagent is stable until the expiration date shown on the vial when stored at 2-8°C and for 2 weeks when stored at 8-25°C.

Opened reagent is stable for 4 weeks at 2-8°C or 2 weeks at 8-25°C provided no contamination occurs.

Reaction Buffer: Unopened buffer is stable until the expiration date shown on the vial when stored at 2-8°C and for 2 weeks when stored at 8-25°C.

Opened buffer is stable for 4 weeks at 2-8°C or 2 weeks at 8-25°C provided no contamination occurs.

SPECIMEN COLLECTION AND STORAGE

Venous blood is collected in 0,13 or 0,11 M tri-Sodium 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[5]. 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 testing. No contact with glass should occur.

PROCEDURE

Refer to appropriate operators manual and insrument specific application for each instrument, for the complete assay procedure instructions.

Material needed but not included in the kit:

- D-Dimer Calibrator plasma (MRX144 or MRX1202)
- D-Dimer Control plasma (see Quality Control below)
- Saline (0,9% NaCl). MediRox recommend the use of MRX184 Sample Diluent (0,9% Saline) for sample and calibrator dilutions. The user need to complete a standard curve for each new lot of reagent and if the control values are outside the determined limit.

QUALITY CONTROL

MediRox recommends the use of normal control plasma (GHI162, GHI164 or MRX171, MRX181) and abnormal control plasma (GHI167B, GHI170, MRX172, MRX173, MRX182, MRX183) for reliable quality control of the performance and at a frequency in accordance with good laboratory practice.

LIMITATIONS AND INTERFERENCES

The D-dimer results should be used together with other clinical and diagnostic information for forming a diagnosis and for patient management.

MRX143 D-Dimer is insensitive to the following substances: hemoglobin up to 10 g/L; bilirubin up to 0,5 g/L; triglycerides up to 20 g/L; low molecular weight heparin up to 100 U/mL and non-fractionated heparin up to 100 U/mL. Turbid or opalescent plasma may cause erratic results and should be interpreted with caution; dilute the sample and re-assay.

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. The reaction buffer includes Heterophilic blocking reagent that reduces unspecific reactions, but users should be aware that there still is a possibility for over-estimation of D-dimer levels for samples with HAMA or rheumatoid factor.

The monoclonal antibody in MRX143 D-Dimer has been screened for its specificity against cross-linked fibrin degradation products. MRX143 D-Dimer has more than 100-fold specificity for D-dimer (Fibrin or purified D-dimer), over Fibrinogen, Fibrinogen D or Fragment E.

RESULTS AND EXPECTED VALUES

The results are reported in ng/mL D-dimer units (DDU). Note that some manufacturers express D-dimer results in Fibrinogen Equivalent Units (FEU). 1 D-dimer unit is approximately 2 FEU (actually 1,74 FEU = 1 DDU[6]).

The normal level of D-dimer in the population is typically below 200 ng/mL[4,7]. 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 intervals or cut-off levels.

Elevated levels of D-dimer are found in patients with deep venous thrombosis (DVT), pulmonary embolism, disseminated intravascular coagulation and truma[8]. D-dimer levels increase during pregnancy[9] and with age[10].

PERFORMANCE CHARACTERISTICS

The performance will depend on the instrument used. The performance data below was obtained with a Sysmex CA-1500 instrument.

MRX143 D-dimer on Sysmex CA-1500 has a reportable range of 50-3500 ng/mL. Precision: CV is less than 4% for low D-Dimer Control plasma and less than 2% for high D-Dimer Control plasma. There is no prozone effect below 100 000 ng/mL.

When compared to another micro-particle enhanced immunoassay, MRX143 D-dimer correlates as follows: y (MRX143 D-dimer on Sysmex CA-1500) = 1,0 x (Biopool/Trinity Auto Dimer on Sysmex CA-1500) - 9,6; r2 = 0,99

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