MediRox

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Revision: 2016-01-01
Changes: New logotype and text format
Supersedes: 2010-11-30

MRX D-Dimer Reagent Art.No: MRX143

INTENDED USE

For the quantitative determination of the fibrin degradation product D-dimer in human citrated plasma using photometric instruments at
wavelength 600-800 nm.
FOR IN VITRO DIAGNOSTIC USE

BACKGROUND AND PRINCIPLE OF METHOD

Structures containing D-Dimer are formed by the plasmin degradation of Factor XIIIa cross-linked Fibrin. Elevated levels of D-Dimer occur in several clinical conditions as Deep Venous Thrombosis(DVT), Pulmonary Embolism (PE) and Disseminated Intravasal Coagulation (DIC)[1,2]. During pregnancy are elevated levels of D-dimer as well as highly elevated levels associated with complications[3].

Photometric measurement of the change in optical density in a sample containing the fibrin degradation product D-dimer, resulting from the reaction and agglutination of microparticle-coupled antibodies against Fibrin D-Dimer.

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 and Sodium Azid (<0,1%)

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 Marterial Safety Data Sheet.

PREPARATION

Allow the reagents to reach working temperature by keeping them at appropriate temperature 10 minutes before use.

- Latex reagent: Invert to mix before use. The reagent is ready for use. Do not shake.
- Reaction Buffer: The reagent is ready for 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 until the expiration date shown on the vials when stored at 2-8°C provided no contamination occurs.
- Unopened and opened Latex Reagent and Reaction Buffer are stable for 7 days at 15-25 °C.

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 [7].
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 user application manual for the complete assay procedure instructions.
Material needed but not included in the kit:

- D-Dimer Calibration Plasma (MRX 144)
- D-Dimer Control (Art no see below)
- Owren Buffer (GHI150) or Saline.

The user must 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

Depending on details of the analysis conduct, you could get falsely low test results in samples with high contents of D-dimer. This is due to the so called antigen-excess phenomenon. The analytical conduct that has been indicated in the application page will consider these effects.

D-Dimer is not affected by UF and LMW Heparin up to 100 U/mL, by Bilirubin up to 0,5 g/L, by Lipids up to 20 g/L and by Hemoglobin up
to 10 g/L.

EXPECTED RESULTS

The D-dimer concentration for healthy individuals is low, often under 200 µg/L[4,5]. It has been indicated that Pulmonary Embolism has increased the levels6 of D-dimer. Patients with proven Deep Venous Thrombosis have D-dimer concentrations of approximately 200 µg/L or higher[4,5] . When suspecting Venous Thrombosis among patients who seek urgent help the probability of Thrombosis is increased with increasing concentrations of D-dimer[5]. High elevated levels can be found in cases of DIC and trauma.

The half-life for D-dimer is approximately 12 hours while circulating. Elevated levels of D-dimer could be found after the completion of the active process.

D-Dimer results can be reported in units of D-dimer (µg/L) or in Fibrinogen Equivalent Units (FEU). 1 µg/L D-Dimer is approx. 2 FEU

Due to many variables which may affect results each laboratory should establish its own reference range. The result should be used with other information, including the clinical context in forming a diagnosis.

For inserts in other languages please contact your local representative.

REFERENCES.

1. Elms, M., et al., Rapid detection of cross linked fibrin degradation products in plasma using monoclonal antibodycoated latex particles. Journal of Clinical Pathology 85: 360-364, 1986
2. Declerk, P., et al., Fibrinolytic response and fibrin fragment D-dimer levels in patients with deep vein thrombosis. Thrombosis and Haemostasis 58: 1024-1029, 1987
3. Ballegeer, V., et al., Fibrinolytic response to venous occlusion and fibrin fragment d-dimer levels in normal and complicated pregnancy. Thrombosis and Haemostasis 58: 1030-1032, 1987.
4. Bounameaux, H., Measurement of plasma D-dimer for diagnosis of deep venous thrombosis. Am J Clin Path 91: 82-85, 1989.
5. Lindahl TL, Lundahl TH, Ranby M, Fransson S-G. Clinical evaluation of a diagnostic strategy for deep venous thrombosis with exclusion by low plasma levels of fibrin degradation product D-dimer. Scand J Clin Lab Invest 58:307-16,1998
6. Van Beek, E., et al., A comparative analysis of D-dimer assays in patients with clinically suspected pulmonary embolism. Thrombosis and Haemostasis 70: 408-413, 1993
7. CLSI. Collection,Transport and Processing of Blood Specimens for testing Plasma-Based Coagulation Assays, 4th Ed., CLSI document H21-A5; Vol .28 No.5.