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Thrombodynamics TDX kit

Instructions for Use

For Research Use Only

Cat. №. TDX-10
For 10 measurements

I. INTENDED USE

Thrombodynamics TDX Kit is an in vitro kit used to perform measurements of spatiotemporal dynamics of fibrin clot formation in blood plasma samples. The kit is intended for professional use in the laboratory with Thrombodynamics Analyser System T2 only.

II. COMPOSITION

1. Reagent I — 10 neutral plastic tubes
2. Reagent II — 10 blue plastic tubes
3. Measurement cuvette — 5 pcs (in individual protective package)
4. Activating insert — 5 pcs (in individual protective package)
5. Instruction for Use — 1 pce

1. Reagent I

Reagent I is a lyophilized solution of protein-inhibitor intended for inhibition of reactions of the contact pathway of coagulation.

Preparation: Reagent I is ready for use as packaged.

2. Reagent II

Regent II is intended for citrated plasma samples recalcification. Reagent II is a lyophilized solution of calcium salt.

Preparation: Reagent II is ready for use as packaged.

3. Measurement cuvette

Measurement cuvette is a plastic vial with two thin channels for plasma samples.

Preparation: Measurement cuvette is ready for use as packaged.

4. Activating insert

Activating insert is a plastic comb with tissue factor immobilized on its bottom end faces.

Preparation: Activating insert is ready for use as packaged.

5. Other kit components

Each kit contains Instructions for Use (this document).

III. STORAGE AND SHELF-LIFE

Tubes with reagents in a sealed pack and activating insert in individual package are stable until the given expiry date indicated on the label when stored at 2÷8 °C.

Reagents should be used within 24 hours after opening.

Activating insert and measurement cuvette should be used immediately after package opening.

Do not use expired reagents.

IV. WARNINGS AND PRECAUTIONS

Do not touch the bottom surface of the activating insert in order to avoid damage of the coagulation activation agent.

The reagents contained in this kit are for *in vitro* use only. Do not ingest!

Wear gloves when handling all kit components. All kit components should be handled in compliance with the respective biosafety regulations and must be disposed after use in the same way as hospital waste. Utilize reagents according to the current country legislation.

Do not use the reagents produced by other manufacturers.

V. ADDITIONAL ITEMS REQUIRED BUT NOT PROVIDED

1. Thrombodynamics Analyser System T2.
2. Centrifuge for 1600g with a rotor designed for 5-9 ml test-tubes.
3. Centrifuge for 10 000g with a rotor designed for 1.5-2 ml micro test-tubes (optionally).
4. Single-channel pipettes with disposable tips, designed to handle 5 µl, 120 µl and 1000 µl volumes.

VI. SAMPLE COLLECTION AND PREPARATION

Anticoagulant

For the blood collection it is recommended to use evacuated plastic tubes for coagulation analysis. Blood (9 parts) should be collected into 3.2% (109 mmol/L) or 3.8% (129 mmol/L) sodium citrate anticoagulant (1 part).[1] Laboratory should standardize the concentration of sodium citrate, as variation of measured parameters may occur between these two concentrations (3.2% vs 3.8%).

Evacuated tubes for coagulation analysis from different manufacturers may significantly effect on measurement results[2]. Each laboratory should perform additional studies and get its own normal reference ranges for blood collection system used.

Do not use glass or siliconized glass collection tubes for thrombodynamics measurements.

[1] The deviation from the set volume of blood more than for 10% is prohibited.

[2] Dashkevich et al; *Effect of Pre-Analytical Conditions on the Thrombodynamics Assay;* Thrombosis Research 133 (2014) 472–476

Sample preparation

1. Take appropriate volume of blood (blood volume must be no less than 2.5 ml).

Attention! The first portion of blood (not less than 2ml) after the venipuncture should be discarded or may be taken for other laboratory analysis. Immediately gently mix the collection tube by three to six complete end-over-end inversions to ensure thorough mixing of the specimen with the anticoagulant. Keep the tube with the blood sample at room temperature. **Blood sample should be used within 1 hour after collection.** As no known test method can provide complete assurance that human blood samples do not transmit any infection, all blood specimens should be considered potentially infectious.

2. Centrifuge the capped blood sample tube at 1600 g for 15 minutes.

3. Transfer 40% of the sample liquid volume from the upper plasma layer to a new tube using a pipette with disposable tips (for example, if initial blood volume is 5 ml one should transfer 2 ml of plasma).

4. Centrifuge the tube with plasma sample at 10000 g for 5 minutes or at 1600 g for 20 minutes to get the platelet free plasma (PFP) sample.

5. Transfer 90% of the specimen liquid volume from the upper PFP layer to a new tube using a pipette with disposable tips. PFP specimen should be used within 4 hours after blood collection.

VII. RUNNING THE MEASUREMENTS

Please refer to Thrombodynamics Analyser System T2 user manual for more detailed information about samples handling and running the measurements.

VIII. PREANALYTICAL LIMITATIONS

The procedure of blood collection and storage should be standardized[3].

Avoid:

- using conventional glass test-tubes;
- incorrect anticoagulant : blood ratio;
- delayed mixing of blood and anticoagulant;
- significant deviation of hematocrit from the normal value;
- using the hemolytic, lipemic or icteric samples;
- contamination of samples by tissue components during blood collection.

[3] Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline Fifth Edition by Clinical and Laboratory Standards Institute (CLCI) H21-A5 Vol.28 No.5.

IX. QUALITY CONTROL PROCEDURES

Quality control procedures are required to ensure the proper system performance. For this purpose a control sample should be tested in Thrombodynamics Analyser System according to the standard measurement procedure. Test result for the quality control sample should be within a range corresponding to the control material.

Please refer to Thrombodynamics Analyser System T2 user manual for more detailed information about control samples preparation and running the quality control measurements.

Each laboratory should also follow local quality assurance procedures.