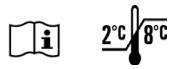
For research use only. Not for use in diagnostic procedures.

RISTOtest

for platelet aggregation studies

RISTO reagent kit

REF **08116644 001**



Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim, Germany
www.roche.com

2015-02, V 3.0 English US-RUO

Product Description

The RISTOtest reagent is a lyophilized preparation of ristocetin, stock concentration 10 mg/mL.

Test principle

RISTOtest reagent contains ristocetin. Ristocetin is an antibiotic known to induce thrombocytopenia and platelet agglutination. Platelets bind to VWF by means of GpIb receptors in the presence of ristocetin. In vitro ristocetin forms complexes with VWF which bind to GpIb and trigger platelet activation and aggregation.

Material provided

REF 08116644 001: 3 vials for 1.0 mL. Lyophilized reagent containing ristocetin: 10 mg/mL.

Materials required (but not provided)

1. Platelet aggregometer
2. Purified water (distilled or deionized)
3. Aggregometer test cells with stir bars
4. Micropipettes – 0.5 µL to 100 µL required for reagents
5. Pipettes – 100 µL to 1 mL required for blood samples, saline and purified water
6. Physiological saline (NaCl 0.9 %) for the dilution of whole blood sample

Instrumentation

The RISTOtest reagent will perform as described when used on the Multiplate® Analyzer. Follow the manufacturer's instructions.

Precautions and warnings

The RISTOtest reagent is for research use only. Not for use in diagnostic procedures. Not for injection or ingestion.

Exercise the normal precautions required for handling all laboratory material.

Disposal of all waste material should be in accordance with local guidelines.

Avoid foam formation in all reagents and sample types.

Reagent preparation

Carefully reconstitute each vial of RISTOtest reagent with 1.0 mL of high purity (distilled or deionized) water. Gently swirl and allow vial to stand closed for 10 minutes at 18-25 °C. Swirl the vial carefully to produce a homogeneous solution before use – do not shake! Avoid the formation of foam.

To achieve maximum stability after reconstitution, pipette ≥ 100 µL aliquots of the reagent into micro test tubes for daily use.

Storage and stability

Store at 2-8 °C.

The lyophilized reagents are stable up to the stated expiration date.

For optimal handling, reconstituted reagent may be aliquoted and the aliquots stored frozen at (-25) - (-15)°C. If reconstituted reagent is not aliquoted into micro test tubes, the original vial should be stored in an upright position. Reconstituted vials should remain tightly closed when not in use.

Stability of the reconstituted reagent:	
at 18-25 °C	24 hours
at 2-8 °C	7 days
at (-25) - (-15)°C	4 weeks
after one time thawing at 18-25 °C	24 hours

Protect reagent from exposure to light, air and elevated temperature ranges.

Sample collection

Blood collection should be performed with caution to avoid prolonged venous stasis and using a large-bore needle during draw. Avoid foam formation in the blood collection tube. Gently invert the collection tube 4 to 5 times to ensure complete mixing of the content. Do not freeze or refrigerate samples. Do not preheat the blood before analysis.

Collect samples into sterile evacuated tubes with non-wettable lining containing 1/10 volume of 3.2 % buffered sodium citrate. Avoid foam formation in the blood collection tube. Always ensure citrated blood collection tubes are filled to the indicated fill volume, in order to avoid excessive citrate levels.

Alternatively, commercial hirudin blood collection tubes (REF 08128812 001) may be used.

The anticoagulant used for blood sample collection significantly affects the results of the test. The blood collection system must be standardised at each centre. It is only possible to compare the results of an individual sample when the same sample anticoagulant (i.e. citrate, lithium-heparin or hirudin) is employed.

Test procedure

Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Test procedure for hirudinized–anticoagulated or citrated blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted RISTOtest reagent	50 µL
Measuring time	6 minutes

Final concentration: 0.77 mg/mL ristocetin.

Temperature conditions and incubation times must be precisely observed.

Note: A partial recalcification of the sample when citrated blood is analyzed (as recommended for TRAPtest or ADPtest) may lead to disaggregation during the analysis. The reason for this phenomenon is unclear. The use of saline-$CaCl_2$ solution (instead of the use of saline solution) for the analysis of RISTOtest is therefore not recommended.

It is important that the tip of the micropipette is immersed in the sample when the reagent is injected.

When using the Multiplate® electronic pipette in auto mode follow the test instructions displayed by the Multiplate® software.

Quality Control

Laboratories should follow generally accepted quality control practices when proficiency testing is not available. It is good laboratory practice to run a drug-free normal control whenever reagents are reconstituted or thawed.

Limitations - interferences

Samples should be analyzed within the period of 0.5-3 hours after blood collection.

The platelet count in the test sample must be above 100,000 when testing in whole blood.

The saline solution (NaCl 0.9%) must not contain any additives such as methyl ester. This can cause false-positive results.

It is important to pay close attention to temperatures and incubation times. The use of non-preheated saline diluent solution or the introduction of shorter incubation times may skew results.

Manufacturer

Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim, Germany
www.roche.com

Distributor

DiaPharma Group, Inc.
8948 Beckett Road
West Chester, OH 45069-2939
USA
www.diapharma.com

2015-02, V 3.0 English