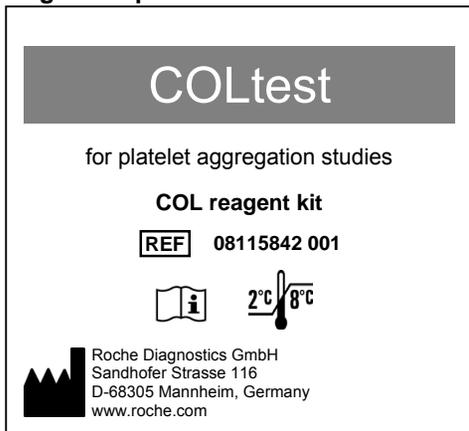


**For research use only. Not for use in diagnostic procedures.**



2015-02, V 3.0 English US-RUO

**Product description**

The COLtest reagent is a lyophilized preparation of collagen, stock activity equivalent to 100 µg/mL.

**Test principle**

The COLtest reagent contains collagen (type I), which activates the platelets via their collagen receptors. Following binding of collagen to its receptors, arachidonic acid is released, which is the substrate of the platelet enzyme cyclooxygenase. Cyclooxygenase transforms arachidonic acid into thromboxane A2, a potent platelet activator.

**Material provided**

REF 08115842 001: 3 vials for 1.0 mL.

Lyophilized reagent containing collagen: activity equivalent to 100 µg/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 or NaCl/CaCl<sub>2</sub> solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or NaCl/CaCl<sub>2</sub> solution (08115974 001) for the dilution of whole blood sample

**Instrumentation**

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

**Precautions and warnings**

The COLtest 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 COLtest 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.

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.

**Do not freeze the reconstituted reagent.**

Stability of the reconstituted reagent:	
at 18-25 °C	24 hours
at 2-8 °C	7 days

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, standard lithium-heparin tubes or 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 citrated blood:	
NaCl/CaCl <sub>2</sub> solution (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted COLtest reagent	20 µL
Measuring time	6 minutes

Test procedure for lithium-heparin-anticoagulated or hirudin-anticoagulated blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted COLtest reagent	20 µL
Measuring time	6 minutes

Final concentration of collagen equates to an activity of 3.2 µg/mL.

Temperature conditions and incubation times must be precisely observed.

**Note:** 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.

Many drugs potentially interfere with platelet function.

**Manufacturer**

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