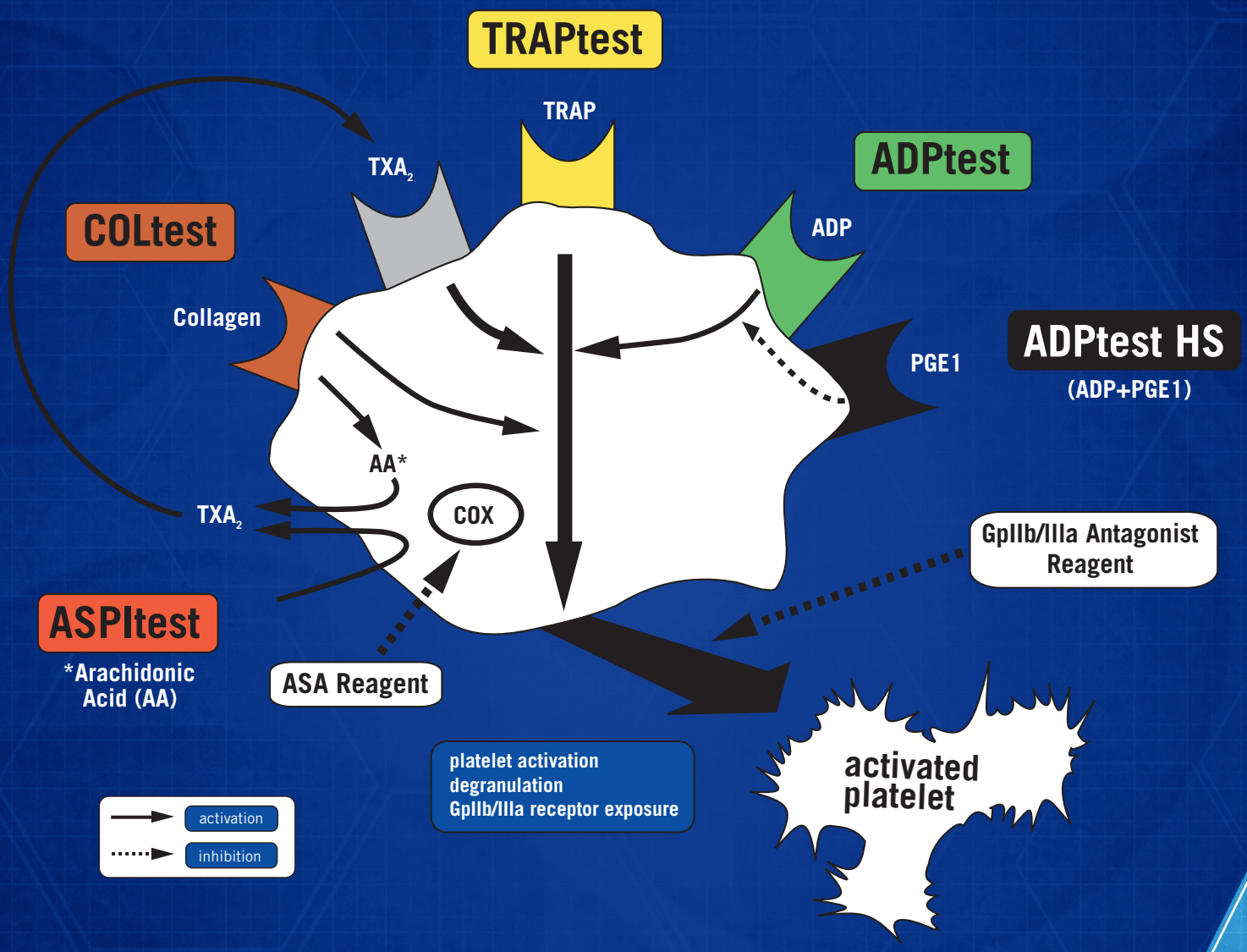
MULTIPLATE®

PACKAGE INSERTS



diapharma

800.526.5224

info@diapharma.com

For research use only. Not for use in diagnostic procedures

Hirudin Blood Tube

Hirudin blood tubes

REF 06675751 001 50 x 3.0 ml

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

2015-02, V 3.0 English US-RUO

Product description

Hirudin, a thrombin inhibitor allows anticoagulation of blood without interference with physiological calcium levels.

The specified concentration of hirudin in the blood collection tubes is > 15 µg/ml.

Packages

REF 06675751 001: 50 x 3.0 mL tubes with dried sprayed hirudin; anticoagulant: recombinant hirudin: >15 ug/mL

Storage and stability

Store tubes at 4-25°C. Avoid exposure to direct sunlight.

Note: Deviation from recommended storage conditions may lead to impairment of the tube quality.

Warnings and precautions

Do not use tubes if foreign matter is present!

1. Handle all biological samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility.
2. Obtain appropriate medical attention in the case of any exposure to biological samples (for example through a puncture injury), since they may transmit HIV, viral hepatitis, or other blood-borne pathogens.
3. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
4. Transferring a sample from a syringe to a tube is not recommended.
5. If blood is collected through an intravenous (IV) line, ensure that the line has been cleared of IV solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from IV fluid contamination.
6. Do not use tubes after their expiration date.

Venipuncture technique and specimen collection

Equipment required for specimen collection

1. The appropriate amount of hirudin tubes.
2. Butterfly blood collection system, needle and tube holder.
3. Practice general safety precautions, using gloves and appropriate apparel for protection from exposure to blood-borne pathogens.
4. Alcohol swab for cleansing site.
5. Tourniquet.
6. Adhesive plaster or bandage.
7. Sharps disposal container for safe disposal of used needle.

Prevention of backflow

To prevent backflow from the tube into the research subject's arm, observe the following precautions:

1. Place research subject's arm in a downward position.
2. Hold tube with the cap uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube contents do not touch cap or end of the needle during venipuncture.
5. Use of a butterfly system or similar catheter between the research subject and the blood collection tube.

Specimen collection procedure

1. Remove the cover over the valve section of the needle.
2. Thread the needle firmly into the tube holder. Attach the butterfly blood collection system with its luer adapter part.
3. Apply tourniquet
4. Prepare venipuncture site with an appropriate antiseptic.
5. Place research subject's arm in a downward position.
6. Remove needle shield of the butterfly system.
7. Perform venipuncture.

Note: It is recommended to use a no-additive discard tube as first tube.

8. Push tube into the holder and onto the needle valve puncturing the rubber diaphragm. Centre tubes in holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss.
9. When the tube is full and blood flow ceases, remove it from holder and **gently invert the tubes at least 5 times** to reach a proper mix of anticoagulant and blood.

Note: Inadequate mixing of tubes may result in platelet clumping, clotting and/or incorrect test results.

10. Optionally, fill further tubes by repeating steps 8 and 9. Follow your facility's protocol and the above named warnings and precautions in order to terminate specimen collection procedure accordingly.

The tube cap can be removed by a simple and cautious pull action.

Literature

In literature the use of citrate as anticoagulant for platelet function analysis is discussed controversially. Concerns are, that citrate depletes calcium and by reducing free calcium levels inhibits platelet function.

In several publications hirudin was used as anticoagulant in concentration ranges of 5-75 µg/ml.

Manufacturer

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www.diapharma.com

2015-02, V 3.0 English

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

Liquid Control Set

quality control verification
of impedance aggregometry

REF **06675999** 190

2°C 8°C

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

2012-07, V 2.0 English US-RUO

Product description

For use as an assayed quality control verification of the resistance measure of impedance aggregometry.

Test principle

Whole blood impedance aggregometry is based on the measurement of a change in electrical impedance caused by the aggregation of blood platelets on a pair of electrodes. The specific evaluation and assessment of the instrument to detect a change in the electrical current may be tested using artificial control material.

The liquid control set consists of two fluids, “Solution 1” and “Solution 2”, of different ionic strengths. The mixing of the fluids in various proportions results in a change of electrical conductivity which is recorded as a change in impedance in the Multiplate® analyzer.

The set contains enough control material to test the level 1 and level 2 controls for all five channels of the Multiplate® analyzer.

Materials Provided

REF 06675999 190: Liquid Control Set

Solution 1: 2 x 4.0 ml
Solution 2: 1 x 2.0 ml

Materials required (but not provided)

1. Platelet aggregometer
2. Purified water (distilled or deionized)
3. Aggregometer test cells with stir bars
4. Pipettes – 100 µL to 1 mL

Instrumentation

The Liquid Control will perform as described when used with the Multiplate® aggregometer. Follow the manufacturer’s instructions.

Precautions and warnings

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.

Reagent Preparation

The reagents are provided in ready-to-use form.

The three tubes must be preheated for 20 minutes prior to use in the preheating positions of the Multiplate® analyzer.

Storage and stability

Liquid quality control solutions must be stored at 2-8°C. The set is stable until the expiry date printed on the tube label when stored under these conditions.

Note: Opened tubes must be used within 24 hours of opening.

Test procedure

Preheat the reagents for 20 min at 37°C in the preheating positions of the Multiplate® analyzer prior to use. Run measurements for level 1 and level 2 controls as follows:

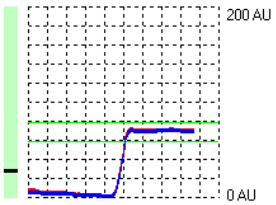
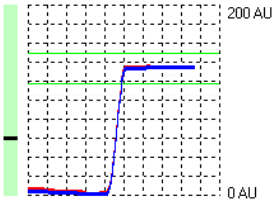
Test procedure for liquid quality controls	
Level 1	**Level 2**
Load all 5 channels with Multiplate® test cells	
Attach the sensor cables to the test cells	
Add 600 µl of “Solution 1” into each channel	
3 min incubation phase (select <F2:Start timer>)	
Select **<F3: Start test>** for all channels	
select <F2:Start timer> again, and **wait for the first 3 min of measuring time**	
Add 100 µl of “Solution 2” **onto** the surface of “Solution 1”.	**Add 200 µl** of “Solution 2” **onto** the surface of “Solution 1”.
Do not immerse the pipette tip into “Solution 1” to avoid air bubbles.	
Wait for the completion of 6 min test time	
Print out and compare aggregation results with expected values	

Note: It is important to precisely follow this procedure. The use of non-preheated solutions or shorter incubation times may skew results. It is important that “Solution 2” is pipetted **onto** the surface of “Solution 1”.

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

Quality Control

Expected values for the liquid quality control analyses, which are marked by two horizontal green lines in the graphic window, are as follows:

Expected values of liquid quality control
Level 1
59.1-78.7 AU

Level 2
117.9-149.6 AU


If results of a liquid control analysis are not within the expected range, repeat the analysis. If a channel’s results repeatedly fall outside of the expected range lock the appropriate channel in the Multiplate® software (menu *Multiplate -> Channel administration*) and contact the manufacturer or local Multiplate® representative for service.

Limitations

The liquid quality control is an artificial quality control of the Multiplate® analysis. The quality of the electronic parts and sensors of the Multiplate® system as well as the quality of the optional electronic pipette is assessed. The liquid control does not assess the appropriate stirring of the sample or the proper performance of aggregation reagents.

Manufacturer

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Distributor

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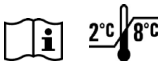
For research use only. Not for use in diagnostic procedures

$NaCl/CaCl_2$

for platelet aggregation studies

REF **06675972** 190



Roche Diagnostics GmbH
Sandhofer Strasse 116
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www.roche.com

2012-07, V 2.0 English US-RUO

Product description

The $NaCl/CaCl_2$ diluent is a mix of calcium chloride (3 mM) and physiological saline (0.9%).

For use as a sample diluent in platelet aggregation studies with the Multiplate® platelet function analyzer under reduced calcium concentrations associated with the use of citrated blood samples.

Principle

Citrate is commonly used as an anticoagulant in blood collection systems for coagulation testing due to its ability to deplete calcium and inhibit the coagulation of the specimen. Reduced calcium levels are a potential concern in platelet testing as they may inhibit platelet function. Therefore it is recommended to partially re-calcify citrated samples with this diluent solution for testing in the Multiplate®. The 3 mM $CaCl_2$ diluent solution enhances the calcium levels of the sample while maintaining the anticoagulant effect of the citrate.

The NaCl/CaCls diluent is a mix of calcium chloride (3mM) and physiological saline (0.9%). The solution is recommended when running the ADPtest, ADPtest HS, COLtest ot TRAPtest in citrated blood samples on the Multiplate® analyzer.

Materials provided

REF 06675972 190: 10 each containing 5 mL of $NaCl/CaCl_2$ solution

Instrumentation

The $NaCl/CaCl_2$ diluent will perform as described when used with the Multiplate® aggregometer. Follow the manufacturer's instructions.

Precautions and warnings

Ensure proper storage conditions. Use the contents of opened tubes within one week of opening. Discard the tube if there is a suspicion of contamination with other substances.

Reagent preparation

The $NaCl/CaCl_2$ diluent is packaged ready-for-use. Prior to use in a test, the diluent must be pre-warmed to 37°C by placing the tube in the pre-heating position of the Multiplate® instrument for a minimum of 10 minutes.

Storage and stability

Store tubes at 2-8°C.

The product is stable until the expiry date on the tube label when stored ar 2-8°C. Use the content of opened tubes within one week of opening.

Sample collection

Blood collection should be performed with caution to avoid prolonged venous stasis and using a large-bore needle during draw. Also 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. Always ensure citrated blood collection tubes are filled to the indicated fill volume, in order to avoid excessive citrate levels.

Test procedure

Refer to the appropriate Operator's Manual for analyzer specific assay instructions.

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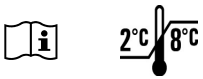
For research use only. Not for use in diagnostic procedures.

ADPtest

for platelet aggregation studies

ADP reagent kit

REF **06675794** 190



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www.roche.com

2015-02, V 3.0 English US-RUO

Product description

The ADPtest reagent is a lyophilized preparation of adenosine-5'-diphosphate (ADP), stock concentration 0.2 mM.

Test principle

When added to a platelet sample, ADP triggers platelet activation via platelet's ADP receptors. Exposure to exogenous ADP will cause normal platelets to release endogenous ADP from their granules and result in irreversible aggregation.

Materials provided

REF 06675794 190: 3 vials for 1.0 mL. Lyophilized reagent containing adenosine-5`-diphosphate: 0.2 mM.

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/$CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation, or or NaCl/$CaCl_2$ solution (REF 06675972 190), for the dilution of whole blood sample

Instrumentation

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

Precautions and warnings

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

The solution should be clear and colorless.

Note: Due to risk minimization procedures the vacuum in the vials was replaced by an inert gas.

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, standard lithium-heparin tubes or commercial hirudin blood collection tubes (REF 06675751 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/$CaCl_2$ solution (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted ADPtest 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 ADPtest reagent	20 µL
Measuring time	6 minutes

Final concentration: 6.5 µM ADP.

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 to 3 hours after blood collection.

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

The saline (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.

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2015-02, V 3.0 English US-RUO

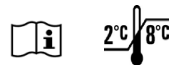
For research use only. Not for use in diagnostic procedures.

Prostaglandin E1

for platelet aggregation studies

PGE1 reagent kit

REF **06675905** 190



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2014-10, V 3.0 English US-RUO

Product description

The PGE reagent is a lyophilized preparation of prostaglandin E1, stock activity equivalent to 300 nM.

Test principle

PGE1 is a natural platelet inhibitor which triggers an increase in cAMP levels in the platelet. cAMP is a so-called second messenger, i.e. an intracellular signalling molecule. A decrease of the cAMP level in the platelet leads to platelet activation. An increase of the cAMP level counteracts platelet activation.

Prostaglandin E1 Reagent is used in combination with ADPtest reagent. The addition of 20 µL PGE1 to the ADPtest (9.4 nM PGE1 final concentration) induces a moderate inhibition of platelet activation in normal blood samples, but a significant increase of sensitivity of the ADPtest to platelet inhibition by substances that affect platelet aggregation through ADP receptor binding. Therefore this modified test is named ADPtest HS (high sensitivity).

Material provided

REF 06675905 190: 3 vials for 1.0 mL.

Lyophilized reagent containing prostaglandin E1: activity equivalent to 300 nM.

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/$CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or NaCl//$CaCl_2$ solution (**REF 06675972** 190) for the dilution of whole blood sample

Instrumentation

The PGE1 reagent will perform as described when used on the Multiplate® Analyzer. Follow the manufacturer's instructions.

Precautions and warnings

The PGE1 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 PGE1 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.

The solution should be clear and colourless.

Note: The vials are filled with an inert gas instead of a vacuum.

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.

Blood samples should be collected in sterile standard lithium-heparin tubes or commercial hirudin blood collection tubes (REF 06675751 001). There is no experience for this reagent with the use of citrated blood.

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. lithium-heparin or hirudin) is employed.

Test procedure

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

Test procedure for ADPtest HS with hirudin-coagulated or lithium-heparin-coagulated blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
PGE1 reagent (reconstituted)	20 µL
ADPtest reagent (reconstituted)	20 µL
Measuring time	6 minutes

Final concentration of PGE1:9.4 nM.

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.

Manufacturer

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2014-10, V 3.0 English

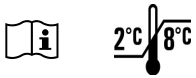
For research use only. Not for use in diagnostic procedures.

ASPItest

for platelet aggregation studies

ASPI reagent kit

REF **06675816** 190



Roche Diagnostics GmbH
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2015-02, V3.0 English US-RUO

Product description

The ASPItest reagent is a lyophilized preparation of arachidonic acid (AA), stock concentration 15 mM.

Test principle

When added to a platelet sample, arachidonic acid triggers platelet activation via a platelet's cyclooxygenase pathway. Arachidonic acid is the substrate of the platelet enzyme cyclooxygenase. Cyclooxygenase transforms arachidonic acid into thromboxane A2, a potent platelet activator.

Materials provided

REF 06675816 190**:** 3 vials for 1.0 mL. Lyophilized reagent consisting of arachidonic acid: 15 mM.

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 (NaCl 0.9 %) and purified water
6. Physiological saline (NaCl 0.9%) for irrigation for the dilution of whole blood sample

Instrumentation

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

Precautions and warnings

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

The solution is slightly yellow. The color does not indicate a reduction of function.

Note: Due to risk minimization procedures the vacuum in the vials was replaced by an inert gas.

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°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	24 hours
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. Also 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 06675751 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 lithium-heparin-anticoagulated, hirudin-anticoagulated or citrated blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted ASPItest reagent	20 µL
Measuring time	6 minutes

Final concentration: 0.5 mM arachidonic acid.

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 to 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 solution or the introduction of shorter incubation times may skew results.

Many drugs potentially interfere with platelet function.

Manufacturer

Roche Diagnostics GmbH,
Sandhofer Strasse 116,
D-68305 Mannheim, Germany
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Distributor

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8948 Beckett Road
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www.diapharma.com

2015-02, V 3.0 English US-RUO

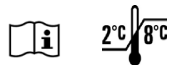
For research use only. Not for use in diagnostic procedures.

COLtest

for platelet aggregation studies

COL reagent kit

REF **06675832** 190



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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 06675832 190: 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/$CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or NaCl/$CaCl_2$ solution (**REF 06675972** 190) 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 06675751 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/$CaCl_2$ 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-antocaogulated 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

Roche Diagnostics GmbH
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Distributor

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2015-02, V 3.0 English

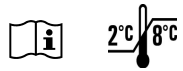
For research use only. Not for use in diagnostic procedures.

RISTOtest

for platelet aggregation studies

RISTO reagent kit

REF **06675867** 190



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2015-02, V 3.0 English US-RUO

Product Descripiton

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 06675867 190: 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 06675751 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

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Distributor

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2015-02, V 3.0 English

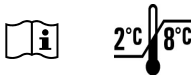
For research use only. Not for use in diagnostic procedures.

TRAPtest

for platelet aggregation studies

TRAP reagent kit

REF **06675883** 190



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2015-02, V 3.0 English US-RUO

Product description

The TRAPtest reagent is a lyophilized preparation of thrombin receptor activating peptide-6 (TRAP-6), stock concentration 1 mM.

Test principle

TRAP-6 is a potent platelet activator and stimulates platelet aggregation via the thrombin receptor PAR-1. This leads to a strong platelet activation that may be inhibited by the presence of thrombin receptor antagonists or GpIIb/IIIa receptor antagonists.

Materials provided

REF 06675883 190: 3 vials for 1.0 mL. Lyophilized reagent containing TRAP-6: 1 mM.

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 $NaCl/CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or $NaCl/CaCl_2$ solution (REF 06675972 190) for the dilution of whole blood sample

Instrumentation

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

Precautions and warnings

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

The solution should be clear and colorless.

Note: Due to risk minimization procedures the vacuum in the vials was replaced by an inert gas.

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, standard lithium-heparin tubes or commercial hirudin blood collection tubes (REF 06675751 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:	
$NaCl/CaCl_2$ solution (prewarmed to 37 °C)	300 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
Reconstituted TRAPtest 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 TRAPtest reagent	20 µL
Measuring time	6 minutes

Final concentration: 32 µM TRAP-6.

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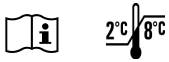
For research use only. Not for use in diagnostic procedures.

ASA Reagent

for use as quality control in platelet aggregation function testing

ASA reagent kit

REF **06675921** 190



Roche Diagnostics GmbH
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2015-02, V 4.0 English US-RUO

Product description

The ASA Reagent (acetylsalicylic acid) is a lyophilised preparation of acetylsalicylic acid, stock concentration 30 mg/mL.

Test principle

ASA Reagent contains acetylisalicylic acid (30 mg/mL). Upon addition to the blood sample the platelet cyclooxygenase pathway is blocked and cyclooxygenase dependent Multiplate® tests are inhibited, especially ASPItest and COLtest. Addition of ASA Reagent to the blood sample leads to reduced aggregation responses in the ASPItest and COLtest.

This allows the assessment of an abnormal response in these tests.

Material provided

REF 06675921 190: 3 vials, each for 1.0 mL. Lyophilized reagent containing acetylsalicylic acid: 30 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 or $NaCl/CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or $NaCl/CaCl_2$ (**REF 06675972** 190) for the dilution of whole blood sample
7. ASPItest (**REF 06675816** 190)
8. COLtest (**REF 06675832** 190)

Instrumentation

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

Precautions and warnings

The ASA 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 the content of one vial of ASA Reagent by adding of 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 homogenous solution before use – do not shake! Avoid the formation of foam.

Keep all vials tightly closed when not in use. Minimize exposure to light, air and elevated temperatures.

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 the 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 06675751 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 ASPItest and ASA Reagent	
Test procedure for hirudin-anticoagulated, heparin-anticoagulated, or citrated blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
ASA Reagent (reconstituted)	20 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
ASPItest reagent (reconstituted)	20 µL
Measuring time	6 minutes

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

Test procedure for COLtest and ASA Reagent	
Test procedure for citrated blood:	
$NaCl/CaCl_2$ solution (prewarmed to 37 °C)	300 µL
ASA Reagent (reconstituted)	20 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
COLtest reagent (reconstituted)	20 µL
Measuring time	6 minutes

During incubation time the cyclooxygenase of the platelets in the sample is inhibited by acetylsalicylic acid.

Final concentration: 1 mg/mL acetylsalicylic acid.

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. A normal blood sample can be used as a control of the activity and stability of the reagent.

Limitations - interferences

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

The saline (NaCl 0.9%) must not contain any additives such as methyl ester.

It is important to pay close attention to temperatures and incubation times. The use of non-preheated saline or $NaCl/CaCl_2$ diluent solution or the introduction of shorter incubation times may skew results.

Manufacturer

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2015-02, V 4.0 English US-RUO

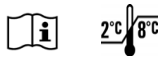
For research use only. Not for use in diagnostic procedures.

GpIIb/IIIa Antagonist Reagent

for use as quality control in platelet aggregation function testing

GpIIb/IIIa antagonist reagent kit

REF **06675948** 190



Roche Diagnostics GmbH
Sandhofer Strasse 116
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2015-02, V 3.0 English US-IVD

Product Description

The GpIIb/IIIa reagent is a liquid reagent containing synthetic GpIIb/IIIa antagonist.

The reagent is employed in combination with the Multiplate® activating reagent TRAPtest, ADPtest, ASPItest and COLtest. Addition of GpIIb/IIIa Antagonist Reagent to a blood sample leads to strongly reduced aggregation in the TRAPtest, ADPtest, ASPItest and COLtest.

Test principle

The GpIIb/IIIa Antagonist Reagent contains a synthetic inhibitor of the platelet GpIIb/IIIa receptor with a molecular weight of 495 g/mol at a concentration of 50 µg/mL. Blocking the GpIIb/IIIa receptor leads to diminished aggregation in the Multiplate® tests. This allows the assessment of a positive control (strongly inhibited aggregation).

Material provided

REF 06675948 190: 3 vials, each of 0.5 mL.

Liquid reagent containing synthetic GpIIb/IIIa Antagonist: molecular weight 495 g/mol in a concentration of 50 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 $NaCl/CaCl_2$ solution and purified water
6. Physiological saline (NaCl 0.9 %) for irrigation or $NaCl/CaCl_2$ (**REF 06675972** 190) for the dilution of whole blood sample
7. TRAPtest (**REF 06675883** 190)
8. ADPtest (REF 06675794 190)
9. ASPItest (REF 06675816 190)
10. COLtest (REF 06675832 190)

Instrumentation

The GpIIb/IIIa Antagonist Reagent will perform as described when used on the Multiplate® Analyzer. Follow the manufacturer's instructions.

Precautions and warnings

The GpIIb/IIIa Antagonist 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

The reagent is ready for use.

Storage and stability

Store at 2-8 °C.

The reagents are stable up to the stated expiration date. Vials should be stored in an upright position.

Stability of the reagent after opening:	
at 18-25 °C	27 hours
at 2-8 °C	30 days

Keep all vials tightly closed when not in use. 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 the 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 06675751 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.

Example: TRAPtest with the addition of GpIIb/IIIa Antagonist Reagent.

Pipette procedures: Add 20 µL of GpIIb/IIIa Antagonist Reagent into the sample before the addition of the agonist.

Test procedure for TRAPtest and GpIIb/IIIa Antagonist Reagent	
Test procedure for hirudinized and lithium-heparinized blood:	
Saline solution, 0.9 % (prewarmed to 37 °C)	300 µL
GpIIb/IIIa Antagonist Reagent	20 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
TRAPtest reagent (reconstituted)	20 µL
Measuring time	6 minutes

Pipette procedures: Add 20 µL of GpIIb/IIIa Antagonist Reagent into the sample before the addition of the agonist.

Test procedure for TRAPtest and GpIIb/IIIa Antagonist Reagent	
Test procedure for citrated blood:	
$NaCl/CaCl_2$ solution (prewarmed to 37 °C)	300 µL
GpIIb/IIIa Antagonist Reagent	20 µL
Sample (18-25 °C)	300 µL
Incubation	180 seconds
TRAPtest reagent (reconstituted)	20 µL
Measuring time	6 minutes

Final concentration: 1.6 µg/mL GpIIb/IIIa Antagonist.

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. A normal blood sample can be used as a control of the activity and stability of the reagent.

Limitations – interferences

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

The saline solution (NaCl 0.9%) must not contain any additives such as methyl ester.

It is important to pay close attention to temperatures and incubation times. The use of non-preheated saline or $NaCl/CaCl_2$ solution or the introduction of shorter incubation times may skew results.

Manufacturer

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Distributor

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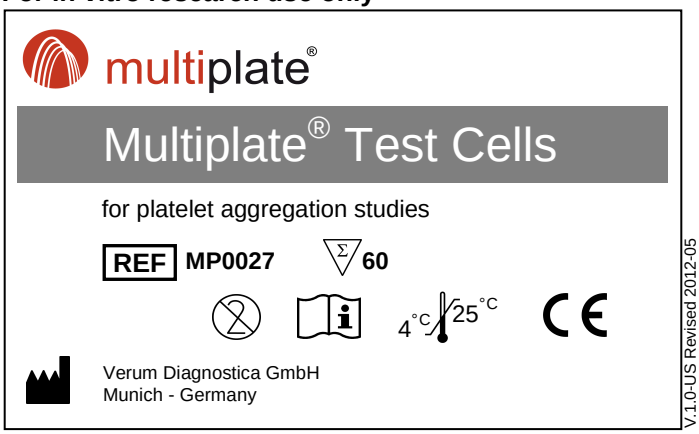
2015-02, V 3.0 English

For in vitro research use only



Intended use

For single use in platelet aggregation studies with the Multiplate® platelet function analyzer with sample volumes of 300 µl whole blood.

Storage and stability

Store the product at 4-25℃. Avoid exposure to air, moisture or direct sunlight. Reseal opened boxes of primary PET packaging accordingly. **Use test cells of opened PET boxes within one month after opening.**

Warnings and precautions

Test cells are single use products. Do not reuse. Do not use volumes for analyses below the minimum volume of 600 µl.

General precautions should be followed when handling specimen and all contaminated materials, e.g. wear gloves, minimize exposure of specimen and reagents to the skin. Dispose of all waste materials according to the local regulations.

Note: Avoid touching electrode wires when handling new unused test cells and make sure that the stirring bar freely rotates at the bottom of the test cell when inserted in the measuring position.

Performance of the analysis

Follow the instructions in the Multiplate® user manual, short instructions manual and instructions for use (IFU) for the Multiplate® reagents.

Test procedure

The minimum volume of the test cell is 600 µl.

Add 300 µl saline 0,9% (preheated at 37℃)
Add 300 µl whole blood (preferably hirudin or lithium heparin anti-coagulated blood, stored at room temperature)
→ 3 minutes incubation time
Add the appropriate amount of agonist
→ Start test → 6 minutes measuring time

Manufacturer

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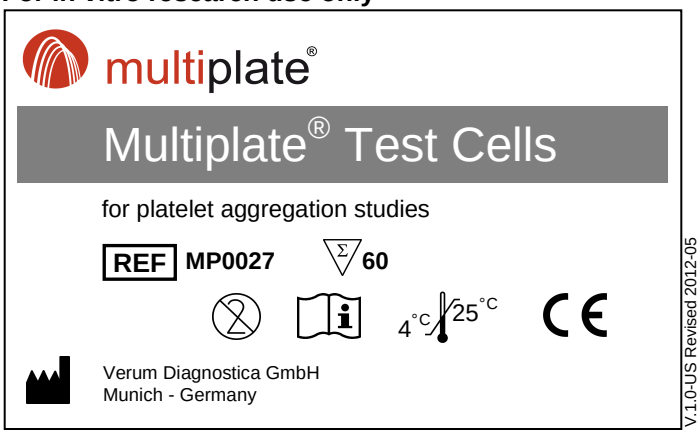

Intended use

For single use in platelet aggregation studies with the Multiplate® platelet function analyzer with sample volumes of 300 µl whole blood.

Storage and stability

Store the product at 4-25℃. Avoid exposure to air, moisture or direct sunlight. Reseal opened boxes of primary PET packaging accordingly. **Use test cells of opened PET boxes within one month after opening.**

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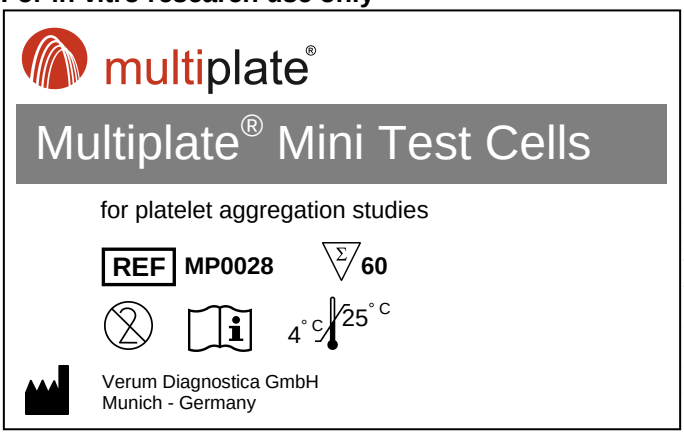

Intended use

For single use in platelet aggregation studies with the Multiplate® platelet function analyzer for low sample volumes of 175 µl whole blood.

Storage and stability

Store the product at 4-25°C. Avoid exposure to air, moisture or direct sunlight. Reseal opened boxes of primary PET packaging accordingly. **Use mini test cells of opened PET boxes within one month after opening.**

Warnings and precautions

For in vitro research use only. Test cells are single use products. Do not reuse. Do not use volumes for analyses below the minimum volume of 350 µl.

General precautions should be followed when handling specimen and all contaminated materials, e.g. wear gloves, minimize exposure of specimen and reagents to the skin. Dispose of all waste materials according to the local regulations.

In the mini test cells during the analysis a smaller blood volume is present compared to the standard test cells. Therefore lower aggregations are found. An analysis with 25 samples of healthy volunteers on average 22% lower aggregations were found using the mini test cells compared to the standard test cells. Therefore reference ranges and target ranges should be determined separately for the mini test cells and standard test cells.

Note: Avoid touching electrode wires when handling new unused test cells and make sure that the stirring bar freely rotates at the bottom of the test cell when inserted in the measuring position.

Performance of the analysis

Follow the instructions in the Multiplate® user manual, short instructions manual and instructions for use for the Multiplate® reagents.

Agonist volumes

For use of the same final concentrations of the standard test assays described in the reagents box inserts please reduce the reagent volumes as follows:

ADPtest / ASPItest / COLtest / TRAPtest:	**12 µl**	RISTOtest high:	**29 µl**
		RISTOtest low:	**7 µl**

Test procedure

The minimum volume of the test cell is 350 µl.

Add 175 µl saline 0,9% (preheated at 37°C)
Add 175 µl whole blood (preferably hirudin or lithium heparin anti-coagulated blood, stored at room temperature)
→ 3 minutes incubation time
Add the appropriate amount of agonist
→ Start test → 6 minutes measuring time

Manufacturer

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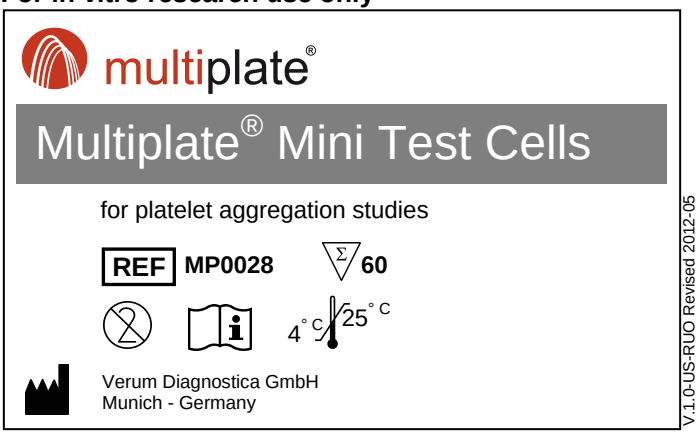

Intended use

For single use in platelet aggregation studies with the Multiplate® platelet function analyzer for low sample volumes of 175 µl whole blood.

Storage and stability

Store the product at 4-25°C. Avoid exposure to air, moisture or direct sunlight. Reseal opened boxes of primary PET packaging accordingly. **Use mini test cells of opened PET boxes within one month after opening.**

Warnings and precautions

For in vitro research use only. Test cells are single use products. Do not reuse. Do not use volumes for analyses below the minimum volume of 350 µl.

General precautions should be followed when handling specimen and all contaminated materials, e.g. wear gloves, minimize exposure of specimen and reagents to the skin. Dispose of all waste materials according to the local regulations.

In the mini test cells during the analysis a smaller blood volume is present compared to the standard test cells. Therefore lower aggregations are found. An analysis with 25 samples of healthy volunteers on average 22% lower aggregations were found using the mini test cells compared to the standard test cells. Therefore reference ranges and target ranges should be determined separately for the mini test cells and standard test cells.

Note: Avoid touching electrode wires when handling new unused test cells and make sure that the stirring bar freely rotates at the bottom of the test cell when inserted in the measuring position.

Performance of the analysis

Follow the instructions in the Multiplate® user manual, short instructions manual and instructions for use for the Multiplate® reagents.

Agonist volumes

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