ADP 1 mM

For *in Vitro* diagnostic use only

Test for the evaluation of platelet aggregation on whole blood induced by ADP.

I. INTENDED USE
ADP is for use in routine platelet aggregation studies for the evaluation of platelet dysfunction or platelet activation.

II. PRINCIPLE
Platelet aggregation test, carried out in vitro on to PRP or Whole Blood, is devoted to studies the platelets capacity of mutual adhesion.
This behaviour is activated by adding to PRP or Whole Blood some suitable aggregating agents kept under constant agitation. It is strictly correlated to calcium ions presence and one or more plasmatic factors, one of this being probably Fibrinogen. Aggregation study in whole blood is based on to the evaluation of the electric resistance changes. Two electrodes while immersed in the sample are rapidly covered with platelets which, at the very first contact, appear in shape of monolayer. When the aggregating agent is added, additional platelets tend to attach the monolayer previously formed, determining an impedance increase between the two electrodes.
The aggregation induced by exogenous ADP is primary and reversible aggregation. The normal platelets release endogenous ADP from its granules. The release of endogenous ADP occurs in a second wave of aggregation, that is irreversible.

III. REAGENTS AND MATERIALS **Each kit contain:**
1. Lyophilized ADP.
2. Diluent A: buffer for dilution with TRIS, pH 7,3.

MATERIAL REQUIRED BUT NOT SUPPLIED
- Blood collection tubes, centrifuge tubes, tubes and pipettes for drawing up the blood, all in siliconized glass or plastic.
- Aggregometer.

IV. STORAGE
Store tightly closed in refrigerator (2-8°C. The kit is stable until expiration date printed on the package label.

V. SAMPLE COLLECTION
Collect the blood, taking particular care with the venepuncture. Avoid excessive stasis by slowly drawing up the blood with the syringe and slowly expelling it (after having removed the needle), into the collection tube; avoid haemolysis. Carry out the venepuncture with a plastic syringe and mix 9 volumes of blood with 1 volume of trisodium citrate 3,8% in a plastic or siliconized tube. The sample is to be processed immediately or after collection taking within 3 hours.

VI. TEST PROCEDURE
Reconstitute one vial with 0,5 ml of Diluent A. The lyophilized reagent once reconstituted is stable for 1 month at -20°C. To avoid repeated thawing and freezing it is advised to subdivide the solution into aliquots of 0,1 ml and freeze.
The ADP concentration necessary to obtain whole blood platelet aggregation is higher than the one used for PRP platelet aggregation. It is advisable to use concentrations ranging from 10 - 20 µM to get a platelet aggregation of 10 – 15 **ohm.**
Add 10-20 µl of ADP (prepared as previously described) to 1 ml of whole blood. Put in the pipette tip down to the bottom of the cuvette and strongly eject.
Record platelet aggregation response for a minimum of 5 minutes.

VII. INTERPRETING THE RESULTS
As the normal absolutes values are not available yet, for whole blood aggregation, it is recommended for each laboratory to establish their own normal ranges in order to compare with aggregation curves taken from pathological subjects.
NOTE: The following Normal Ranges were obtained from various laboratories and pubblications. They should be used **as a guideline only**.

Normal ranges in Whole Blood (WB) ± 2 σ			
Reagent	**Conc.**	**Aggregation (ohms)**	**ATP (nmole)**
ADP	5 µM	1 – 17	0 – 0,70
	10 µM	6 – 24	0,38 – 1,71

VIII. PERFORMANCES
This product will perform as described prior to its expiration date when procedural and storage directions are followed.
Linearity, accuracy, precision.
Platelet aggregation induced by common aggregating reagents (ADP, Arachidonic Acid, Collagen and Adrenaline) is a nonlinear test system for some parameters: Lag Phase, Primary Slope, Secondary Slope, biphasic response and disaggregation. The non-linearity is caused by many factors such as the reaction chemistry and instrumentation. Platelet aggregation measures a response rate or activity that is not a quantitative measure of the reactants or their concentration.
In platelet aggregation, accuracy is a relative parameter and is dependent on the test system.
The limitations of platelet aggregation make it difficult to provide typical precision or reproducibility ranges.

IX. PRECAUTIONS
Carry out the test in subjects on an empty stomach, 8 hours no smoking, not assuming any medical remedies containing Acetylsalicylic Acid for one week or *other drugs interfering the platelet aggregation.*

X. NOTE
To test at the same time optical test on whole blood and the release of ATP with **bioluminescent** technique should work on a **lumi-aggregometer**. (Example 700-2). Refer to the Technical Manual and the instructions in User Manual of instrument.

XI. REFERENCES
Refer to the Technical Manual **M3115xxx BE-0 07/11**

CONTENT	**REF. 311500WA**
ADP 1 mM	6 x 0,5 mL
Diluent A	1 vial x 5,0 mL
Instruction for use	1 item

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (LXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

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