BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

ADP REAGENT

Adenosine-5'-Diphosphate

REF 101312

IVD 2°C 8°C

INSTRUCTIONS FOR USE

ENGLISH - EN

PRODUCT DESCRIPTION

ADP Reagent is a lyophilized preparation of Adenosine-5'-Diphosphate. It is an essential component in platelet aggregation. ADP acts as an agonist or activator, binding to platelet receptors and triggering a series of biochemical events that lead to platelet activation and aggregation.

ADP Reagent has been optimized for use with Light Transmission Aggregometers. It may also be used with other turbidometric or impedance analyzers, and flow cytometers.

INTENDED PURPOSE

ADP Reagent (Adenosine-5'-Diphosphate) is for routine use in eliciting a concentration dependent activation or aggregation response in a Platelet Rich Plasma (PRP) test sample.

DETECTION / MEASUREMENT

ADP Reagent is used, in conjunction with other diluents and control samples, to measure changes of the light transmission in a Platelet Rich Plasma (PRP) test sample.

PRODUCT FUNCTION

ADP Reagent provides insight into different aspects of platelet function / quality. This Reagent aids in accessing various acquired and inherited platelet disorders or the efficacy of anti-platelet therapies.

SPECIFIC INFORMATION PROVIDED

ADP Reagent is not intended for the detection of a specific disorder, condition, or risk factor.

ADP Reagent plays a pivotal role in platelet activation and aggregation. When ADP binds to specific receptors on the platelet surface, such as P2Y1 and P2Y12, it initiates intracellular signaling cascades. This activation induces rapid changes in platelet shape and the release of calcium ions through P2Y1 receptors, while P2Y12 activation sustains the response, ensuring stable aggregation. ADP Reagent is utilized to stimulate platelet activation and aggregation precisely by interacting with these ADP receptors. By observing platelet aggregation in response to ADP, clinicians can assess platelet function / quality related to abnormalities in platelet activation and aggregation. This process is crucial for understanding clot formation dynamics and evaluating the efficacy of anti-platelet therapies in preventing thrombotic events. ADP prompts the release of secondary mediators like Thromboxane A_2 (TXA_2), further amplifying platelet activation and aggregation.

AUTOMATION

ADP Reagent is intended for use in semi-automated and automated Light Transmission Platelet Aggregometers. This Reagent may also be used with other turbidometric or impedance analyzers, and flow cytometers.

QUALITY / QUANTITY

There are no primary standards for ADP Reagent . The responses to this reagent are concentration dependent. A known normal donor should be tested with each new lot of ADP Reagent. Standards organizations classify ADP induced platelet aggregation as semi-quantitative or semi-qualitative.

ADP Reagent comes packaged as 3 x 0.5 mL vials. The working concentration of ADP is 200 µM.

SPECIMEN TYPE

The test specimen is prepared from sodium citrate anti-coagulated whole blood. The test sample is Platelet Rich Plasma (PRP). The test blank is Platelet Poor Plasma (PPP).

ADP Reagent may be used with human or animal Platelet Rich Plasma (PRP) for routine platelet aggregation tests. Results are based on the concentration, extent, and rate of aggregation compared to a Platelet Poor Plasma (PPP) blank.

TESTING POPULATION

- Human: The prevalence of platelet disorders is global and may vary by race, ethnicity, blood type, and other factors. The incidence is variable.
- Anti-Platelet Drugs: The prevalence and incidence are variable. 4% of the population over the age of 40 take Anti-Platelet Drugs, other than Aspirin. 33% (For Adults > 40); 16% Dual Anti-Platelet Therapy (DAPT); and 8% Anti-Platelet Therapy (APT).
- Inherited Platelet Disorders: The prevalence and incidence are variable. There are 60 types; 75 Known Genes; Frequency 5/1000; Estimated 1-2% of the population.
- Animal: The prevalence and incidence are species dependent.

IN VITRO DIAGNOSTIC

ADP Reagent is an in vitro diagnostic reagent intended for Professional Laboratory Use Only. It is not intended for injection or ingestion.

INTENDED USER

ADP Reagent is intended for Professional Laboratory Use by qualified personnel.

TEST PRINCIPLE

When introduced to a stirred, 37°C Platelet Rich Plasma (PRP) test sample, exogenous Reagents such as ADP stimulate platelets, prompting them to undergo shape change and aggregate. This initial aggregation is called primary aggregation and is reversible. However, normal platelets possess the ability to release endogenous ADP from their granules, leading to a secondary, irreversible wave of aggregation. The Light Transmission Platelet Aggregometer effectively captures these changes by displaying parameters such as lag phase, shape change, and the rate and extent of aggregation over a predetermined testing period.

CALIBRATORS AND CONTROLS

There are no calibrators or controls required for ADP Reagent. A known donor sample should be tested with each lot of ADP Reagent. Responses are concentration dependent.

REAGENT LIMITATIONS

ADP Reagent will perform as specified when the Instructions for Use are followed. The reagent must be used prior to the expiration date printed on each vial.

REAGENTS PROVIDED

REF 101312: 3 vials of ADP Reagent (0.5 mL)

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- Purified Water (Distilled, Deionized, Reagent Grade), pH 5.3 – 7.2 for reconstitution
- TRIS Buffered Saline (TBS) or 0.85% physiological saline for dilutions

NOTE: USING BLOOD BANK SALINE WILL CAUSE ERRONEOUS RESULTS.

MATERIALS AND ACCESSORIES

- Platelet Aggregometer *(Follow the Manufacturer's Instructions for Use)*
- Centrifuge
- Electronic Pipette
- Pipette Tips ②
- Aggregometer Test Tubes *(Siliconized)* ②
- Aggregometer Stir Bars *(Plastic Coated)* ②
- Plastic Sample Tubes and Caps *(for Dilutions)* ②

NOTE: DISPOSABLE ITEMS SUCH AS TEST TUBES, STIR BARS, SAMPLE TUBES, AND CAPS ARE FOR ONE TIME USE ONLY

STORAGE AND STABILITY

ADP Reagent does not require temperature protection during shipment.

Upon receipt, store ADP Reagent at 2 – 8° C in its original packaging.

Reconstituted ADP Reagent is stable for 30 days when stored in its' tightly capped, original container at 2 – 8° C.

STERILITY

NON STERILE

ADP Reagent is not a sterile product. Be careful not to contaminate the product when pipetting the reconstituted or aliquoted reagents.

WARNINGS AND PRECAUTIONS

Wear PPE in accordance with laboratory policies and practices when handling ADP Reagent.

Follow standard precautions when preparing test specimens and samples.

Handle ADP Reagent with care to avoid contamination during use.

Avoid reagent evaporation by limiting air – liquid exchange surfaces.

To ensure optimum test results, a known donor control sample should be run consecutively, without interruption.

To preserve reagent stability, store remaining reagent in its' tightly capped, original container.

Dispose of post-test materials in accordance with applicable regulations and laboratory policies.

NOTE TO USER: ANY SERIOUS INCIDENT THAT OCCURS IN RELATION TO THIS PRODUCT SHALL BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND / OR PATIENT ARE ESTABLISHED.

INFECTIOUS MATERIAL STATUS

ADP Reagent does not contain any infectious materials. Test specimens and samples must be considered infectious and should be handled as if capable of transmitting infection. After testing, test specimens and samples must be disposed of in compliance with applicable regulations and laboratory policies.

SPECIAL FACILITIES

ADP Reagent does not require the use of special facilities within a laboratory environment.

PREPARATION FOR USE

NOTE: ADP REAGENT MUST BE AT ROOM TEMPERATURE (15 – 28° C) PRIOR TO RECONSTITUTION. STORED REAGENTS MUST BE BROUGHT TO ROOM TEMPERATURE PRIOR TO USE.

RECONSTITUTION

The working concentration of reconstituted ADP is 200 µM. All final concentrations are based on adding 25 µL of ADP Reagent to a 225 µL Platelet Rich Plasma (PRP) test sample.

- Reconstitute ADP Reagent with 0.5 mL of Purified Water.
- Invert gently to mix.
- Reconstituted ADP Reagent should be kept capped prior to use.

DILUTIONS

For BIPHASIC AGGREGATION

To demonstrate biphasic ADP aggregation, the Platelet Rich Plasma (PRP) may be tested with various dilutions of the reagent. Further dilutions may be made to determine the threshold concentration. The threshold concentration is the lowest concentration that elicits a primary aggregation response.

NOTE: FOR DILUTIONS, USE TRIS BUFFERED SALINE (TBS) OR 0.85% PHYSIOLOGICAL SALINE.

TABLE 1: ADP DILUTION CHART

ADP REAGENT	TRIS BUFFERED SALINE	WORKING CONCENTRATION	FINAL CONCENTRATION
———	———	200 µM	20 µM
125 µM	125 µM	100 µM	10 µM
62 µM	188 µM	50 µM	5 µM
25 µM	225 µM	20 µM	2 µM

NOTE: FOR DILUTIONS, USE TRIS BUFFERED SALINE (TBS) OR 0.85% PHYSIOLOGICAL SALINE.

PATIENT PREPARATION

Patients should refrain from taking aspirin or using aspirin-containing medications and products, as well as other medications, supplements, or energy drinks known to affect platelet function for 7 – 10 days prior to specimen collection. Ingestion of fatty foods, dairy products, and smoking should be avoided for 12 hours before specimen collection.

NOTE: CONSULTATION WITH A PHYSICIAN IS REQUIRED PRIOR TO MAKING ANY MEDICATION CHANGES.

SPECIMEN COLLECTION

The specimen should be collected with care to avoid stasis, hemolysis, contamination by tissue fluid and exposure to glass. Specimens must be kept at room temperature. Release the tourniquet as soon as blood begins to flow into the collection device.

PRACTICE STANDARD PRECAUTIONS THROUGHOUT THE SPECIMEN COLLECTION, SAMPLE PREPARATION, AND ANALYTICAL PROCESSES. DISPOSE OF SHARPS AND BIOHAZARDOUS WASTE IN ACCORDANCE WITH APPLICABLE REGULATIONS AND LABORATORY POLICIES.

Evacuated Specimen Collection Technique

- Use a 21g or 23g winged needle collection set for specimen collection
- Draw blood into plastic evacuated specimen collection tubes containing 3.2% (0.11 M) sodium citrate anti-coagulant
- Gently mix the specimen collection tube 4 - 5 times by inversion
- Write collection time on the specimen label
- Maintain specimen collection tubes at room temperature
- Remix specimen collection tubes prior to centrifugation

Syringe Collection Technique

- Use a 21g or 23g winged needle collection set for the venipuncture
- Draw 9.0 mL of blood into a plastic syringe, avoiding excess suction
- Clamp the winged needle tubing and disconnect the syringe
- Immediately and gently dispense the blood specimen into a plastic (polypropylene) tube containing 1.0 mL of 0.11 M sodium citrate anti-coagulant. The blood to anticoagulant ratio is 9 parts blood to 1 part anti-coagulant
- Cap the plastic tube
- Gently mix the specimen collection tube 4 - 5 times by inversion
- Write collection time on the specimen label
- Maintain specimen collection tubes at room temperature
- Remix specimen collection tubes prior to centrifugation

NOTE: WHEN THE PATIENT'S HEMATOCRIT IS LESS THAN 30% OR GREATER THAN 55%, THE BLOOD TO ANTI-COAGULANT RATIO MUST BE ADJUSTED. BLUE TOP EVACUATED SPECIMEN COLLECTION TUBES MUST CONTAIN 3.2% (0.11 M) SODIUM CITRATE ANTICOAGULANT. WHICH IS THE RECOMMENDED CONCENTRATION FOR PLATELET FUNCTION STUDIES.

SAMPLE PREPARATION

Platelet Rich Plasma (PRP)

- Centrifuge the anti-coagulated blood at 150 x g for 10 minutes at room temperature
- Examine the plasma layer for red cells
- If red cells are present, re-centrifuge for an additional 5 minutes
- Use a Pipette to transfer the PRP to a plastic container labeled PRP
- Remove the PRP from a point just below the middle of the PRP volume for consistent platelet count *(THE TOP OF THE VOLUME HAS A LOWER PLATELET COUNT AND THE BOTTOM IS MORE CONCENTRATED)*
- Cap the container
- Allow the container to stand at room temperature

Platelet Poor Plasma (PPP)

- Centrifuge the remaining PRP blood specimen at 2500 x g for 20 minutes
- Use a Pipette to transfer the PPP to a plastic container labeled PPP
- Cap the container
- Allow the container to stand at room temperature

ASSAY PROCEDURE

Routine Aggregation Procedure

NOTE: THIS IS A GENERAL PROCEDURE. FOLLOW THE INSTRUCTIONS FOR USE PROVIDED BY THE MANUFACTURER OF THE AGGREGOMETER IN USE.

Prepare a Blank for Each Patient

NOTE: EACH PATIENT MUST HAVE THEIR OWN BLANK. ONE PATIENT'S BLANK CANNOT BE USED FOR ANY OTHER PATIENT. THE PATIENT'S BLANK MUST BE PREPARED FROM THE PATIENT'S PLATELET POOR PLASMA (PPP) SPECIMEN. IF THE SAME PATIENT IS BEING TESTED ON MULTIPLE TEST WELLS, THE SAME PATIENT'S BLANK MAY BE USED FOR THOSE TEST WELLS.

- Label a test tube with the letter "B", test well #, and patient ID to identify the Blank
- Pipette 250 µL of Platelet Poor Plasma (PPP) into the test tube *(DO NOT ADD A STIR BAR)*
- Place Blank aside for later use
- Repeat the steps above for each patient

FIGURE 1: ADP NORMAL AGGREGATION

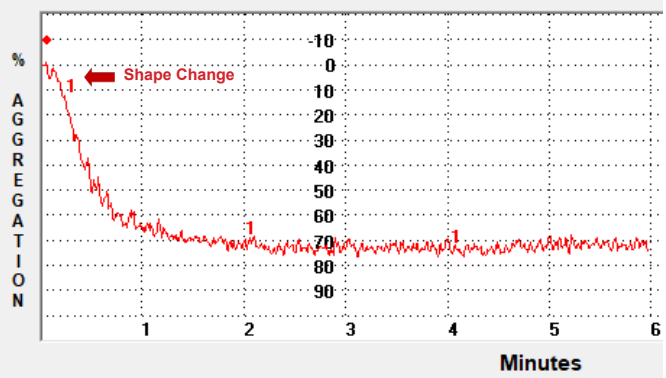
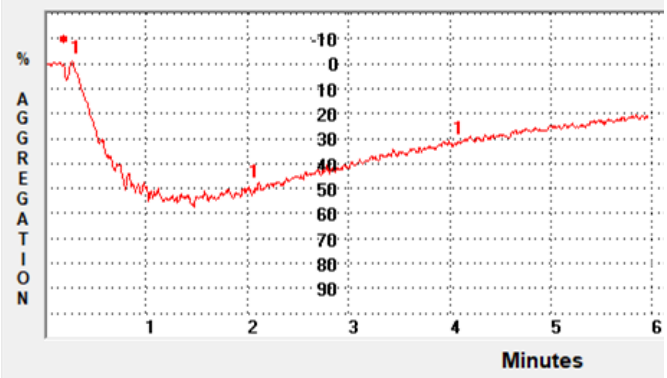


FIGURE 2: ADP ABNORMAL AGGREGATION



Prepare Samples

- Label one to eight new test tubes with each patient ID and test well #
- Place the labeled test tubes into the correct well # 1 - 8 of the stirred sample incubation wells
- Add a stir bar to each test tube
- Pipette 225 µL of Platelet Rich Plasma (PRP) sample into each test tube in the stirred sample incubation wells *(MAKE SURE THERE ARE NO BUBBLES)*
- Select the on-screen timer for each stirred sample incubation well in use and the warming countdown will start
- The samples will incubate at 37º C for the pre-set time
- Set the 100% baseline (Blank)
- Place the appropriate previously prepared patient's Blank test tube into test well # 1
- Select BLANK to activate the test well
- The BLANK button will change to START
- Repeat the steps above for each test well being used for testing

Begin Testing

- Once the countdown timer reaches 0:00, press the timer button to stop each stirred sample incubation well
- Transfer the test tube in the stirred sample incubation well # 1 to test well # 1
- Repeat the step above for each test well, making sure all test tubes remain with their corresponding well #'s during transfer
- Close the pipette guides
- Select START for test well # 1
- Pipette 25 µL of reagent directly into the Platelet Rich Plasma (PRP) test tube in test well # 1 *(DO NOT ALLOW REAGENT TO RUN DOWN THE WALL OF THE TEST TUBE OR PERMIT PIPETTE TIP TO BREAK THE SURFACE OF THE SAMPLE)*
- Select INJECT for test well # 1
- Repeat the steps above for each test well being used for testing
- The test will now run for the pre-set time *(OTHER MANUFACTURER'S TEST PROCEDURES MAY SPECIFY DIFFERENT TIMES OR VOLUMES)*

⚠ *NOTE: USE A KNOWN DONOR AS A CONTROL SAMPLE. EACH LABORATORY SHOULD ESTABLISH AND VALIDATE ITS OWN TEST PROTOCOL AND VERIFY THE RESULTING PERFORMANCE OF ITS TEST SYSTEM (REAGENTS, INSTRUMENT, AND TEST PROTOCOL).*

QUALITY CONTROL

For platelet aggregation studies, a known donor should be tested in the same manner as the patient to ensure test system performance and consistency. A new control should be included with each test series, and preferably with each new reagent lot or after instrument maintenance. Each laboratory must define its acceptable ranges for its patient population and verify the expected performance of the test system.

RESULTS

Typical aggregation patterns induced by ADP Reagent are illustrated in Figures 1 through 2. When ADP Reagent is used at a final concentration of 20 µM, it induces a large single wave of aggregation in normal Platelet Rich Plasma (PRP). At lower concentrations, ranging from 2 µM to 10 µM, two distinct waves of aggregation may be observed. The primary wave is the immediate response to the exogenous ADP introduced by the reagent, while the secondary wave is due to the release of endogenous ADP from the storage pool of nucleotides within the platelets.

In some normal PRP samples, concentration-dependent disaggregation may be observed, indicating a variable response to different ADP concentrations. Spike marks in the figures indicate the points at which the reagent was added, providing clear reference points for the timing of reagent introduction and its effects on the aggregation process.

LIMITATIONS

In Light Transmission Aggregometry, the presence of red blood cells in the PRP will cause the observed aggregation to be reduced. The presence of platelets in the PPP will cause final aggregation to be increased. Spurious results may occur if the PRP platelet count is less than 75,000 platelets / cumm. PRP platelet counts can only be performed using the hemocytometer method. Compromised samples must be rejected. If the results are abnormal, the test should be repeated on another occasion. Each laboratory must establish reference ranges tailored to the population it serves, and the specific reagent concentrations used.

TABLE 2: ADP RESULTS OBSERVED IN PLATELET FUNCTION DEFECTS

DEFECT	ADP REAGENT
ASPIRIN-LIKE	⬇ or N
THROMBASTHENIA	⬇ ⬇
STORAGE POOL DISEASE	⬇
VON WILLEBRAND SYNDROME	N
BERNARD-SOULIER SYNDROME	N

⬇ = *Reduced Aggregation Resulting From a Decrease or Absence of Secondary Wave*

⬇ ⬇ = *Reduced Aggregation Resulting From a Decrease or Absence of Primary and Secondary Wave*

N = *Normal Response*

EXPECTED VALUES

Each laboratory should establish expected ranges for each reagent at various concentrations used to induce aggregation (Table 3).

TABLE 3: EXPECTED RESULTS FOR PLATELET AGGREGATION RESPONSES IN NORMAL DONORS

Final Aggregation at 6 Minutes

Parameter	Units	ADP REAGENT
Final Concentration		20.0 µM
Primary Aggregation	%	81
Primary Slope		54
Secondary (Biphasic) Aggregation	%	Yes
Secondary Slope		Variable
Area Under The Curve	Minutes	320
Lag Phase	Seconds	< 10
Disaggregation	%	Yes
Maximum Aggregation	%	≥ 89
Final Aggregation	%	63 - 89

⚠ *NOTE: ADJUSTING PLATELET COUNTS IS NOT RECOMMENDED*

ANALYTICAL PERFORMANCE

Platelet aggregation, induced by commonly used reagents like ADP Reagents, is a non-linear test system. Responses are based on the difference between the patient's Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) light transmission and therefore, results are unique to that patient. Certain parameters are more prone to non-linearity than others. These include 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 displays the response rate or activity and does not quantify the reactants or their concentrations. 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.

The variability in linearity, precision and reproducibility of results in ADP Reagent-based test systems, is acknowledged by multiple standards organizations. The commonly accepted CV is ± 15%.

Test to Test Reproducibility:	less than ± 7.5%
Instrument to Instrument Reproducibility:	less than ± 15.0%
Reagent Lot to Lot Variability:	less than ± 10.5%
Laboratory to Laboratory (System to System)	less than ± 12.5%

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SYMBOLS

	Bio-Hazardous
REF	**Catalog Number**
	Caution
CE	**CE Marked & Registered Product**
	Consult Instructions For Use
EC REP	**European Union Representative**
IVD	**In Vitro Diagnostic Device**
	Manufacturer
	Must Read
NON STERILE	**Non-Sterile**
2	**Single Use Only**
	Temperature Limitations
UK CA	**United Kingdom Marked & Registered Product**
UK REP	**United Kingdom Representative**

REVISION HISTORY

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- Modified Testing Instructions
- Implemented IVDR Regulatory Requirements
- Reformatted and Reconfigured to Enhance Operator Use

For a complete product catalog, please visit our website at www.biodatacorp.com or contact our Customer Service Department.

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