BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

EPINEPHRINE REAGENT

REF 101311

Adrenaline

IVD

2°C 8°C

INSTRUCTIONS FOR USE

ENGLISH - EN

PRODUCT DESCRIPTION
Epinephrine Reagent is a stabilized and lyophilized preparation of L-Adrenaline that activates the GP IIa adreno receptor causing platelet aggregation without shape change. Although it can enhance the response of platelets to other agonists, Epinephrine Reagent is a weak (reversible) agonist. It may or may not elicit a response in healthy people.

Epinephrine 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
Epinephrine Reagent (Adrenaline) is for routine use in platelet studies for the evaluation of hypersensitivity of platelets in Platelet Rich Plasma (PRP) and platelet responses to a weak agonist.

DETECTION / MEASUREMENT
Epinephrine 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
Epinephrine 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
Epinephrine Reagent is not intended for the detection of a specific disorder, condition, or risk factor.

Epinephrine Reagent plays a pivotal role in platelet activation and aggregation. Upon binding to specific receptors on the platelet surface, particularly α2-adrenergic receptors, epinephrine initiates intracellular signaling cascades. This cascade induces rapid changes in platelet shape and triggers the release of calcium ions, crucially mediated through α2-adrenergic receptor activation. The sustained response, essential for stable aggregation, is facilitated by α2-adrenergic receptor activation. Epinephrine Reagent is instrumental in precisely stimulating platelet activation and aggregation by interacting with these adrenergic receptors. Observing platelet aggregation in response to Epinephrine Reagent allows clinicians to assess and evaluate platelet function / quality and disorders associated with abnormalities in platelet activation and aggregation. This process is pivotal for comprehending clot formation dynamics and evaluating the effectiveness of anti-platelet therapies in preventing thrombotic events. Epinephrine prompts the release of secondary mediators, further amplifying platelet activation and aggregation.

AUTOMATION
Epinephrine 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 Epinephrine Reagent. The responses to this reagent is concentration dependent. A known normal donor should be tested with each new lot of Epinephrine Reagent. Standards organizations classify Epinephrine induced platelet aggregation as semi-quantitative or semi-qualitative.

Epinephrine Reagent comes packaged as 3 x 0.5 mL vials. The working concentration of Epinephrine is 100 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).

Epinephrine 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 abnormal Epinephrine Reagent aggregation is 16 – 20% in healthy people. It 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. The varying response rates to Epinephrine have been noted across different populations. Studies have demonstrated that Dual Anti-Platelet Therapy and Aspirin can influence Epinephrine-induced platelet aggregation.
- Inherited Platelet Disorders: The prevalence of abnormal epinephrine response in people varies with the defect. The incidence is variable.
- Animal: The prevalence and incidence are species dependent.

IN VITRO DIAGNOSTIC
Epinephrine Reagent is an in vitro diagnostic reagent intended for Professional Laboratory Use Only. This Reagent is not intended for injection or ingestion.

INTENDED USER
Epinephrine 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 Epinephrine 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.

Hyper-reactivity may be demonstrated. If so, the Sticky Platelet Procedure should be followed for confirmation. Not all healthy people will respond to the Epinephrine Reagent.

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

REAGENT LIMITATIONS
Epinephrine 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 101311: 3 vials of Epinephrine 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% physiologic 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
Epinephrine Reagent does not require temperature protection during shipment.

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

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

STERILITY

Epinephrine 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 Epinephrine Reagent.

Follow standard precautions when preparing test specimens and samples.

Handle Epinephrine 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 reagents in its' capped, original containers.

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

Epinephrine 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

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

PREPARATION FOR USE

NOTE: EPINEPHRINE 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 Epinephrine is 100 µM. All final concentrations are based on adding 25 µL of Epinephrine Reagent to a 225 µL Platelet Rich Plasma (PRP) test sample.

- Reconstitute Epinephrine Reagent with 0.5 mL of Purified Water.
- Invert gently to mix.

NOTE: EPINEPHRINE REAGENT MAY APPEAR CLOUDY BUT WILL BECOME CLEAR TO PALE YELLOW WITHIN A FEW MINUTES.

- Reconstituted Epinephrine Reagent should be kept capped prior to use.

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

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 count down will start
- The samples will incubate at 37° 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

FIGURE 1: EPINEPHRINE NORMAL AGGREGATION

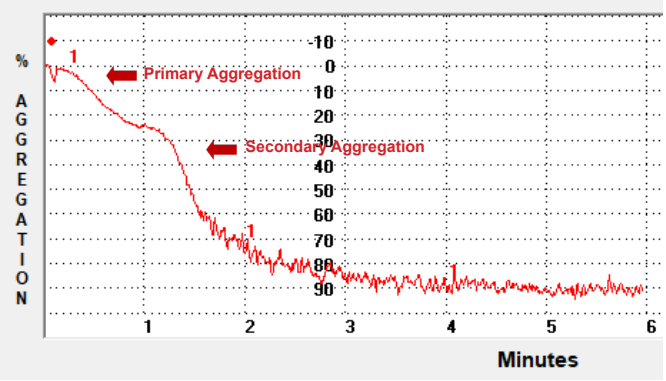
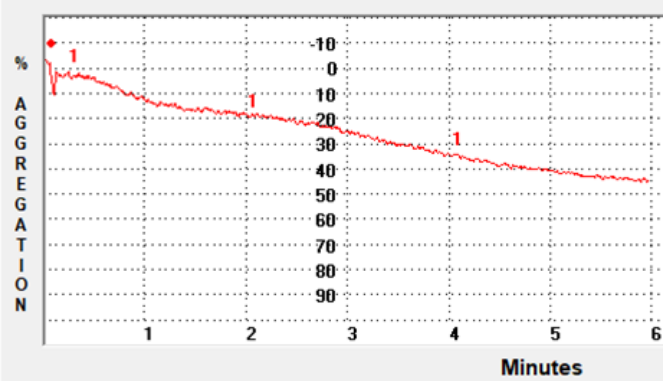


FIGURE 2: EPINEPHRINE NORMAL AGGREGATION



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 Epinephrine Reagent are depicted in Figures 1 and 2, offering a comprehensive view of its effects on Platelet Rich Plasma (PRP). When Epinephrine Reagent is added to normal PRP, it induces a biphasic response characterized by two distinct waves of aggregation. The first wave represents the initial platelet response to the reagent, while the second wave is due to the release of additional platelet agonists from the granules within the platelets, further amplifying the aggregation process.

This biphasic response is a hallmark of healthy PRP samples, indicating normal platelet function. Conversely, abnormal Epinephrine aggregation is identified when the final aggregation is less than 30%, as shown in Figure 2. Such a reduced response may indicate platelet dysfunction or other hematological abnormalities, providing valuable diagnostic information.

Spike indicators in the figures mark the exact points at which the reagent is added, offering clear reference points for the timing of reagent introduction. These markers are essential for correlating the addition of Epinephrine Reagent with the observed aggregation patterns, allowing for precise analysis of its immediate effects on the aggregation process.

EXPECTED VALUES

Each laboratory should establish expected ranges for each reagent at various concentrations used to induce aggregation (Table 2).

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 1: EPINEPHRINE RESULTS OBSERVED IN PLATELET FUNCTION DEFECTS

DEFECT	EPINEPHRINE 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*

TABLE 2: EXPECTED RESULTS FOR PLATELET AGGREGATION RESPONSES IN NORMAL DONORS

Total Aggregation at 6 Minutes

Parameter	Units	EPINEPHRINE REAGENT
Final Concentration		10.0 µM
Primary Aggregation	%	87
Primary Slope		20
Secondary (Biphasic) Aggregation	%	Yes
Secondary Slope		Variable
Area Under The Curve	Minutes	540
Lag Phase	Seconds	0
Disaggregation	%	Yes
Maximum Aggregation	%	≥ 104
Final Aggregation	%	51 - 104

⚠ *NOTE: ADJUSTING PLATELET COUNTS IS NOT RECOMMENDED*

ANALYTICAL PERFORMANCE

Platelet aggregation, induced by commonly used reagents like Epinephrine Reagent, 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 Epinephrine 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

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