BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

COLLAGEN REAGENT

Soluble Calf Skin (Type 1)

REF 101562

IVD

2°C 8°C

INSTRUCTIONS FOR USE

ENGLISH - EN

PRODUCT DESCRIPTION

Collagen Reagent is a lyophilized preparation of Soluble Calf Skin (Type 1). Collagen Reagent induces platelet shape change and activates platelets. The activated platelets then release thrombotic compounds from their granules, which serve to recruit additional platelets to an injury site.

Collagen 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

Collagen Reagent (Soluble Calf Skin, Type 1) is intended for routine use in inducing Platelet Rich Plasma (PRP) responses to activation, aggregation, and inhibition.

DETECTION / MEASUREMENT

Collagen 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

Collagen 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

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

Collagen Reagent initiates platelet activation and aggregation. Upon binding glycoprotein receptors on the platelet surface, particularly glycoprotein VI (GP VI), Collagen sets off intracellular signaling cascades. This triggers rapid changes in platelet shape and the release of calcium ions through GP VI receptors, with sustained activation facilitated by integrin α2β1, ensuring stable aggregation. Utilized to precisely stimulate platelet activation and aggregation, Collagen Reagent interacts with these receptors, providing a means for clinicians to assess platelet function / quality and disorders linked to collagen-induced platelet activation abnormalities. This process is vital for comprehending clot formation dynamics and evaluating the efficacy of anti-platelet therapies inhibiting thrombotic events. Collagen prompts the release of secondary mediators, further amplifying platelet activation and aggregation.

AUTOMATION

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

Collagen Reagent comes packaged as 3 x 0.5 mL vials. The working concentration of Collagen is 1.9 mg / mL.

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).

Collagen 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 of abnormal Collagen Reagent aggregation, contingent on estimated Aspirin usage, reaches up to one third of the population. Both Clopidogrel and the combination of Clopidogrel with Aspirin can influence Collagen-induced platelet aggregation. The incidence is variable.
- Inherited Platelet Disorders: The prevalence and incidence are variable. There are 60 types of inherited platelet disorders that affect approximately 0.3% of the population. Certain inherited platelet defects, such as Glanzmann's Thrombasthenia and Storage Pool Disease, show no response to Collagen Reagent.
- Animal: The prevalence and incidence are species dependent.

IN VITRO DIAGNOSTIC

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

INTENDED USER

Collagen 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, Arachidonic Acid, Collagen, Epinephrine, and Ristocetin 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 Collagen Reagent. A known donor sample should be tested with each lot of Collagen Reagent. Responses are concentration dependent.

REAGENT LIMITATIONS

Collagen 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 107650: 3 vials of Collagen 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

Collagen Reagent does not require temperature protection during shipment.

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

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

STERILITY

NON STERILE

Collagen 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 Collagen Reagent.

Follow standard precautions when preparing test specimens and samples.

Handle Collagen 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' 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

Collagen 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

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

PREPARATION FOR USE

NOTE: COLLAGEN 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 Collagen is 1.9 mg / mL. All final concentrations are based on adding 25 µL of Collagen Reagent to a 225 µL Platelet Rich Plasma (PRP) test sample.

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

FIGURE 1: COLLAGEN NORMAL AGGREGATION

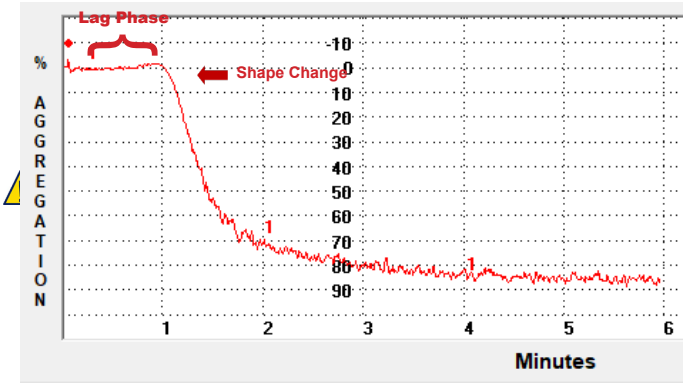
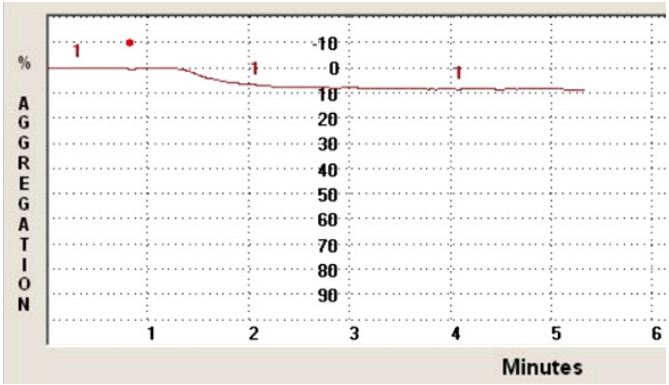


FIGURE 2: COLLAGEN ABNORMAL AGGREGATION



- 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 Collagen Reagent are illustrated in Figures 1 and 2, providing a detailed representation of the reagent's effects on Platelet Rich Plasma (PRP). Following the addition of Collagen Reagent to PRP, an initial lag phase occurs during which no aggregation is observed. After this lag phase, normal platelets will exhibit a noticeable shape change. Following the shape change, a large, single wave of aggregation is observed, demonstrating the robust response of the platelets to Collagen Reagent.

Spike marks in the figures indicate the exact points at which the reagent was added, providing clear reference points for the timing of reagent introduction and its 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).

TABLE 1: COLLAGEN RESULTS OBSERVED IN PLATELET FUNCTION DEFECTS

DEFECT	COLLAGEN REAGENT
ASPIRIN-LIKE	⬇
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*

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: EXPECTED RESULTS FOR PLATELET AGGREGATION RESPONSES IN NORMAL DONORS

Final Aggregation at 6 Minutes

Parameter	Units	COLLAGEN REAGENT
Final Concentration		0.19 mg / mL
Primary Aggregation	%	85
Primary Slope		55
Secondary (Biphasic) Aggregation	%	No
Secondary Slope		0
Area Under The Curve	Minutes	524
Lag Phase	Seconds	< 60
Disaggregation	%	Yes
Maximum Aggregation	%	≥ 99
Final Aggregation	%	61 - 99

⚠ *NOTE: ADJUSTING PLATELET COUNTS IS NOT RECOMMENDED*

ANALYTICAL PERFORMANCE

Platelet aggregation, induced by commonly used reagents like Collagen 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 Collagen 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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