BIO/DATA CORPORATION

155 GIBRALTAR ROAD, HORSHAM, PA 19044 U.S.A
WORLDWIDE: (215) 441-4000 U.S.A.: (800) 257-3282 FAX: (215) 443-8820
An ISO 13485:2003 Registered Company
www.biodatacorp.com EMAIL: customer.service@biodatacorp.com

Instructions for Use

Collagen *SRP*™ Catalog No. 107328

FOR RESEARCH USE ONLY

Product Description

Collagen *SRP* is a synthetic, liquid polypeptide polymer of PHG (PolyPHG,Tripeptide Proline Hydroxyproline Glycine), a Type 1, fibrillar collagen polypeptide.
Collagen SRP specifically reacts with Glycoprotein V1 (GPV1). GPV1 is a 62-k Da type 1 transmembrane glycoprotein that is expressed on platelets and mature megakaryocytes.

Collagen *SRP* is for professional laboratory use.

Principle:

Collagen *SRP* is a synthetic polymer polypeptide reagent that self assembles into the triple helix of Type I fibrillar collagen.
Collagen *SRP* is a potent inducer of platelet activation and aggregation.

Precautions

⚠ **COLLAGEN *SRP*** is for **RESEARCH USE ONLY** and **NOT FOR USE** in diagnostic tests, assays or procedures. **Collagen *SRP*** is not for injection, ingestion or cosmetic use.

⚠ **COLLAGEN *SRP*** does not contain any bacterial, animal or human source material.

⚠ **COLLAGEN *SRP*** conforms to the requirements of MEDDEV.2.14/2, rev 1. Every precaution has been taken to protect the health and safety of the user and other persons.

⚠ Do **not** use tubes or vials other than those included in this kit. Erroneous results may occur.

⚠ Do **not** use Parafilm® to seal or mix vials. Erroneous results may occur.

Materials Provided

1. **Collagen *SRP***, 0.0002 mg/mL (0.2µg/mL), 1 x 1mL
2. **Collagen *SRP***, 0.00005 mg/mL (0.05µg/mL), 1 x 1mL
3. **Collagen *SRP*** Diluent, 2 x 5mL
4. Four polypropylene vials with stoppers for preparing additional dilutions

Reagent Storage

⚠ **Collagen *SRP*** is stable for 1 year when stored at 2° to 8°C.
Collagen *SRP* must be stored at 2° to 8°C when not in use.
Do not freeze Collagen SRP
Do not expose Collagen SRP to temperatures ≥ 25°C except for the 2 minutes of instrument incubation and the test procedures.

Concentrations

Two concentrations of **Collagen *SRP*** are provided:

1. **Collagen *SRP***, 0.00005mg/mL (0.05 µg/mL) is the initial recommended concentration.
2. **Collagen *SRP***, 0.0002mg/mL (0.2 µg/mL) is provided for dilution studies other than 0.00005mg/mL (0.05 µg/mL).
   Refer to Reagent Preparation Table 1 for various working concentrations.
   Prepare desired working concentrations with the **Collagen *SRP*** diluents provided.

Test Procedure for Platelet Aggregation

⚠ Testing must be completed within 4 hours of specimen collection.

⚠ Testing must be performed per the instrument manufacturer's directions and your laboratory policies and procedures.

⚠ Stored **Collagen *SRP*** must be brought to room temperature prior to use.

⚠ Do ***not*** Vortex

⚠ Mix diluted **Collagen *SRP*** thoroughly by inverting four times prior to use.

Instructions for PAP 8E or other LTA Systems requiring 0.25mL total test volume:

1. Place a stir bar into each test tube.
2. Prepare an aggregometer blank by pipetting 0.25mL, platelet poor plasma into a test tube.
3. Pipette 0.225mL platelet rich plasma into a second test tube. Incubate at 37° for 2 minutes.
4. Set, if required, the 0% and 100% baselines according to the manufacturer's instructions for the aggregometer in use.
5. Mix **Collagen *SRP*** thoroughly by inversion. Do ***not*** vortex. Add 0.025mL **Collagen *SRP*** directly into the platelet rich plasma.
   Do not allow reagent to run down the wall of the test tube. Refer to dilution chart for appropriate concentration.
6. Allow the aggregation pattern to generate for 6 minutes.

If total test volume on your LTA System differs, volumes must be adjusted appropriately.

Instructions for LTA systems requiring 0.5 mL total test volume:

1. Place a stir bar into each test tube.
2. Prepare an aggregometer blank by pipetting 0.5mL, platelet poor plasma into a test tube.
3. Pipette 0.45mL platelet rich plasma into a second test tube. Incubate at 37° for 2 minutes.
4. Set, if required, the 0% and 100% baselines according to the manufacturer's instructions for the aggregometer in use.
5. Mix **Collagen *SRP*** thoroughly by inversion. Do ***not*** vortex. Add 0.05mL **Collagen *SRP*** directly into the platelet rich plasma. Do not allow reagent to run down the wall of the test tube. Refer to dilution chart for appropriate concentration.
6. Allow the aggregation pattern to generate for 6 minutes.

For platelet aggregation studies**, Collagen *SRP*** may be used straight from the vial, or may be diluted. Always mix **Collagen *SRP*** thoroughly by inverting four times prior to use or preparing dilutions. Follow the table below to prepare dilutions. Use only the diluent and empty vials provided in the kit. See Table 1.

Prepare working concentrations with the **Collagen *SRP*** Diluent provided in the kit

Table 1: Reagent Preparation Table for Platelet Aggregation

0.00005 Collagen SRP	Starting	Working Concentration		0.0002 Collagen SRP	Starting	Working Concentration
Collagen SRP µL	Diluent µL	(mg/ mL)		Collagen SRP µL	Diluent µL	(mg/ mL)
100	900	0.000005		100	900	0.00002
200	800	0.000010		200	800	0.00004
300	700	0.000015		300	700	0.00006
400	600	0.000020		400	600	0.00008
500	500	0.000025		500	500	0.00010
600	400	0.000030		600	400	0.00012
700	300	0.000035		700	300	0.00014
800	200	0.000040		800	200	0.00016
900	100	0.000045		900	100	0.00018

Performance Characteristics

Performance characteristics have not been established for **Collagen *SRP*.**

Results

Typical results and reference ranges for **Collagen *SRP*** have not been established for any application. Each laboratory must establish its own criteria for test acceptability. Observed results are based on very limited data and may not be representative or reproducible. See Table 2.

Table 2: Platelet Aggregation Responses at Various Concentrations (as observed on limited sample types in Bio/Data Corporation laboratories):

Collagen *SRP* Concentration (mg/mL)	0.5000	0.0500	0.0050	0.0005	0.000250	0.000050	0.000025	0.000005	0.0000025
Slope	58	51	54	58	57	57	50	28	53
Aggregation	80	76	83	86	82	81	77	81	82
Lag Phase	0.1	0.1	0.1	0.1	0.1	0.1	3.5	32	16.5

Limitations

Platelet aggregation measures the rate or activity of platelet response in the presence of a stimulant or agonist. It is not a quantitative measure of reactants or concentrations.

Quality Control

Laboratories should follow generally accepted quality control practices.

Research Use Only (RUO) Products from Bio/Data Corporation

Bio/Data Corporation RUO products are intended for laboratory research only. RUO products are *not* for use in diagnostic tests, assays or procedures. RUO products are *not* intended for ingestion, injection or cosmetic use.

Customers purchasing RUO products acknowledge that there may be risks or hazards associated with the product's handling, storage and use. The laboratory's safety procedures, including the proper use of Personal Protective Equipment should be in effect when working with an RUO product.

Use of RUO products shall be limited to qualified and properly trained laboratory professionals.

Purchasing an RUO product does not convey any license or other intellectual property rights to the customer.

Customers represent and warrant that, through their own data, review and study that the laboratory staff is aware of and trained in the following:

- **Regulations regarding the use of and exposure to Research Use Only Products.**
- **Laboratory policies and practices that mitigate hazards and risks associated with the handling and use of RUO products.**
- **Obligations to warn laboratory staff about the risks and hazards associated with RUO product use; train staff in the proper use of the RUO product and its limitations.**

Printed in the U.S.A. P/N 107401 Rev B