**PRODUCT DESCRIPTION**
Collagen is a lyophilized preparation of soluble calf skin collagen (Type I). The working concentration of the reconstituted reagent is 1.9mg/mL.

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

**PRINCIPLE**
When collagen is added to platelet rich plasma, the platelets adhere to the collagen. Following this adhesion, normal platelets will change their shape, release endogenous ADP, and aggregate.

**PRECAUTIONS**
Collagen is for IN-VITRO DIAGNOSTIC USE ONLY AND NOT FOR INJECTION OR INGESTION.

**MATERIALS PROVIDED**
Collagen, 3 x 0.5mL. Store at 2° to 8° C prior to reconstitution.

**MATERIALS REQUIRED BUT NOT PROVIDED**
1. Platelet Aggregometer
2. Purified water (distilled, deionized or reagent grade), pH 5.3 - 7.2
3. Pipettors (0.5mL, 0.45mL volumes)
4. Disposable Stir bars
5. Aggregometer cuvettes

**INSTRUMENTATION**
Collagen will perform as described when used on most optical platelet aggregometers. Follow the manufacturer's instructions for operating the aggregometer in use.

**SPECIMEN COLLECTION AND PREPARATION OF TEST SAMPLE**
Refer to the current NCCLS Approved Guideline H21 A2 for detailed specimen collection and sample preparation instructions.

1. **PATIENT PREPARATION:**
   - Patients should refrain from taking aspirin or medications containing aspirin, other medications and dietary supplements known to affect platelet function for 7 - 10 days prior to specimen collection. Patients should fast and avoid fatty foods and dairy products for 12 hours prior to specimen collection.

2. **SPECIMEN COLLECTION:**
   - Blood collection should be performed with care to avoid stasis, hemolysis, contamination by tissue fluids, or exposure to glass. Keep specimens at room temperature.
   - Each of the following can cause test results to be inaccurate; and affected specimens should be rejected: hemolysis, RBC contamination, lipemia, chylous, icterus, thrombocytopenia (<75,000/mm³) clots in specimen, and hypofibrinogenemia. Reuse of disposable items may result in inaccurate test results.
   - Observe standard precautions throughout the specimen collection, sample preparation and analytical processes. Dispose of sharps and biological waste in accordance with laboratory policy.
   - Syringe Technique (recommended):
     - a. Use a butterfly needle for the venipuncture.
     - b. Draw 9.0mL of blood into a plastic syringe. Avoid excess suction.
     - c. Remove the needle from the syringe and immediately and gently dispense the blood into a plastic [polypropylene]4 tube containing 1.0mL of 0.11M Sodium Citrate anti-coagulant. The ratio of blood to anti-coagulant must be 9 parts of blood to 1 part anti-coagulant.
     - d. Cover and invert 4-5 times gently to mix.
     - e. Maintain at room temperature (15° to 28°C).

**RESULTS**
Typical Collagen aggregation patterns are illustrated in Figs. 1 and 2. Following addition of Collagen, the platelet count of the PRP should be 250,000 ± 50,000/mm³. The platelet count may be reduced by using PPP prepared from the sample.

NOTE: If using Arachidonic Acid as an agonist, do not adjust the platelet count.

**REAGENT STORAGE**
The reconstituted Collagen is stable for 30 days when stored at 2° - 8°C in its original tightly sealed container.

**TEST PROCEDURE**
Testing must be completed within 4 hours of specimen collection:
1. Place a stir bar in each cuvette.
2. Prepare an aggregometer blank by pipetting 0.5mL platelet poor plasma into a cuvette.
3. Pipette 0.45mL platelet rich plasma into a second cuvette. Incubate at 37°C for 2 minutes.
4. Set, if required, the 0% and 100% baselines according to the manufacturer's instructions for the aggregometer in use.
5. Add 0.05mL Collagen directly into the platelet rich plasma. Do not allow reagent to run down the wall of the cuvette.
6. Allow the aggregation pattern to generate for 5 minutes.

**QUALITY CONTROL**
Laboratories should follow generally accepted quality control practices when proficiency testing is not available.

To assure proper instrument operation and reagent performance, a control specimen should be evaluated each day that tests are performed. The control specimen should be prepared in the same manner as the test specimen. For qualitative platelet aggregation studies, the control should consist of fresh platelet rich plasma collected from a specified and qualified) normal donor who has not ingested aspirin containing compounds within 10 days of testing and has a history of normal platelet function.

**EXPECTED VALUES**
Expected ranges for each reagent at various concentrations used to induce platelet aggregation should be established by each laboratory, see Table 2.

**TYPICAL PLATELET AGGREGATION RESPONSES FOR NORMAL DONORS @ 250,000 PLATELETS/mm³ (total aggregation at 5 minutes)**

<table>
<thead>
<tr>
<th></th>
<th>ADP</th>
<th>Arachidonic Acid</th>
<th>Collagen [Type I]</th>
<th>Epinephrine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Conc.</td>
<td>2,0x10⁵ M</td>
<td>500µg/mL</td>
<td>0.19µg/mL</td>
<td>1,0x10⁶ M</td>
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<tr>
<td>Lag Phase [sec]</td>
<td>&lt;10</td>
<td>&lt;=20</td>
<td>&lt;80</td>
<td>0</td>
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<tr>
<td>Total Aggregation (%@5min)</td>
<td>62-101</td>
<td>65-90</td>
<td>63-109</td>
<td>54-101</td>
</tr>
<tr>
<td>Biphasic Aggregation</td>
<td>concentration dependent</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Other</td>
<td>May show Shape changes</td>
<td>All normal Donors may not Conform</td>
<td>Do not Dilute</td>
<td>All normal Donors may not Conform</td>
</tr>
</tbody>
</table>
LIMITATIONS
A detailed patient history is required for accurate test interpretation. Patients should be questioned
about the recent ingestion of any medication, because a number of prescription and nonprescription
drugs may interfere with platelet aggregation. Substances such as caffeine, tobacco, herbal
extracts (or supplements) and alcohol may affect results.1,2

PERFORMANCE CHARACTERISTICS
Studies have shown that this product will perform as described prior to its expiration date when
procedural and storage directions are followed.

Linearity:
Platelet aggregation induced by common agonists (ADP, Arachidonic Acid, Collagen and
Epinephrine) is a nonlinear test system for the following 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.

ACCURACY, PRECISION AND REPRODUCIBILITY
Accuracy
In platelet aggregation, accuracy is a relative parameter and is dependent on the test system.

Precision and Reproducibility
The limitations of platelet aggregation make it difficult to provide typical precision or reproducibility
ranges. However, there is an experienced based consensus for these parameters (see below).
Each laboratory must establish its own limits for test acceptability.

Test to Test Reproducibility: better than ± 7.5%
Instrument to Instrument Reproducibility: better than ± 15%
Reagent Lot to Lot Variation: better than ± 10.5%
Laboratory to Laboratory (same test system): better than ± 12.5%

REFERENCES
1963.
3. National Committee for Clinical Laboratory Standards. NCCLS: Protection of Laboratory
Wayne, PA.
4. McCabe-White, M and Jennings, LK. Platelet protocols: Research and Clinical laboratory
5. Newhouse, P and Clark, C. The Variability of Platelet Aggregation in Triplet, DA, ed. Platelet
6. National Committee for Clinical Laboratory Standards. NCCLS Collection, Transport and
18-A2. Wayne, PA.
7. Weiss HJ: Aspirin and platelets in drugs and hematologic reactions. Dimitrov and Nodine
8. Triplet DA, Harms CS, Newhouse P, Clark C; Platelet Function. Laboratory Evaluation and
10. Owen CA, Bowie EJW, Thompson JH: The diagnosis of bleeding disorder. Little, Brown and
Co., 1975.

Fig. 1 Normal Aggregation

Fig. 2 Abnormal Aggregation

PRODUCT AVAILABILITY

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>NET CONTENTS</th>
<th>CATALOG NUMBER</th>
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<td>Collagen</td>
<td>3 x 0.5mL</td>
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<td>Arachidonic Acid</td>
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<td>101297</td>
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<tr>
<td>ADP</td>
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<td>BETA/Pak®</td>
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<td>Epinephrine</td>
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