Pepsinogen I Reagent Kit

**Detection of Pepsinogen I in Human Serum or Plasma on Chemistry Analyzers**

**SUMMARY OF TEST PROCEDURE**

<table>
<thead>
<tr>
<th>Figure 1: Procedure Diagram</th>
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<tbody>
<tr>
<td>Sample: 6µl</td>
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<tr>
<td>O.D. Measurement 1</td>
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<tr>
<td>0</td>
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</tbody>
</table>

*Refer to Figure 1 and the package insert for detail*

**INTENDED USE**

**Bioway Chemistry Reagent Series Pepsinogen I Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Pepsinogen I in human serum or plasma on automated clinical chemistry analyzers.

**SUMMARY AND EXPLANATION**

Pepsinogens are inactive precursors of pepsins which are protelytic enzymes in gastric juice and are classified into Pepsinogen I (PG I) and Pepsinogen II (PG II). The ratio between PG I and PG II is a useful indicator that reflects a degree of atrophy of gastric mucosa. However, they are not markers specific for gastric cancer, and should not be used as a substitution of indirect X-ray photography.

**TEST PRINCIPLES**

The Kit utilizes latex-enhanced immunoturbidimetry to measure the PG I level in human serum or plasma. During the test, PG I in the sample binds with the antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of PG I in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

**MATERIALS PROVIDED**

<table>
<thead>
<tr>
<th>Reagents:</th>
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<tbody>
<tr>
<td><strong>R1</strong></td>
<td>(90, 150 or 300 mL) Good's buffer, pH 6.0</td>
</tr>
<tr>
<td><strong>R2</strong></td>
<td>(30, 50 or 100 mL) latex particles coated with mouse anti-human pepsinogen I monoclonal antibody.</td>
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</table>

**MATERIALS NEEDED BUT NOT PROVIDED**

1. Automated chemistry analyzer.
2. PG I calibrator set (available for purchase) and control set (commercially available).

**INSTRUMENT**

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

**STORAGE AND STABILITY**

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable for 1 year when stored properly. R1 and R2 reagents are stable for 1 month at 2-10°C after opening.

**EXPECTED VALUES**

Strong positive: PG I ≤30ng/mL and PG I/PG II ratio ≤ 2.0
Moderate positive: PG I ≤50ng/mL and PG I/PG II ratio ≤ 3.0
Positive: PG I ≤70ng/mL and PG I/PG II ratio ≤ 3.0

<table>
<thead>
<tr>
<th>Table 1: Instrument Parameters*</th>
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<tbody>
<tr>
<td>Calibration method</td>
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<tr>
<td>Wavelength</td>
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<tr>
<td>Test method</td>
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<tr>
<td>Reaction temperature</td>
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</tbody>
</table>

**PRECAUTIONS**

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed according to local regulation.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

**SPECIMEN COLLECTION AND HANDLING**

Follow standard laboratory procedures to collect serum or plasma samples. It is recommended to perform test immediately after sample collection. If the test cannot be done within 24 hours, store sample at -40°C. Avoid repeated freezing and thawing.

**TEST PROCEDURE (see Figure 1)**

**Calibration:** 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

**Test procedure:** see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 6 µl of sample and 180 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Add 30 µl of R2, mix well and incubate at 37°C for 30 seconds.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 582 seconds.
5. Calculate ΔOD = OD 2 – OD 1

**RESULT**

The PG I value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

**EXPECTED VALUES**

Strong positive: PG I ≤30ng/mL and PG I/PG II ratio ≤ 2.0
Moderate positive: PG I ≤50ng/mL and PG I/PG II ratio ≤ 3.0
Positive: PG I ≤70ng/mL and PG I/PG II ratio ≤ 3.0
It is recommended for each laboratory to establish its own expected values.

**QUALITY CONTROL**

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

**LIMITATIONS**

1. The Kit is for in vitro use on automated chemistry analyzers only.
2. Hemolysis samples or samples containing interference substances may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.
4. Do not use the kit as an alternative method of indirect X-ray photography.

**PERFORMANCE CHARACTERISTICS**

**Measurement Range:** 10 – 200 ng/mL

**Precision:** Within Run: CV≤10%; Run-to-Run: CV≤10%

**Accuracy:** 100% ± 15%

**Interference:** no interference detected for: Bilirubin (20.4 mg/dL), hemoglobin (457 mg/dL) and Chyle-Intralipid (2470 formizine turbidity).

**Sensitivity:** The absorbance change is 0.00 to 0.02 for the test of sample containing 0.0 ng/mL PG I and 0.01 to 0.10 for sample containing 50ng/mL PG I.

**REFERENCES**


Not Intended for Sale in the United States.