Please use the reagent after reading this package insert

Pepsinogen Ⅰ

Quantitative turbidimetric latex assay for the measurement of Pepsinogen Ⅰ

【Important notice】

Pepsinogen Ⅰ and Pepsinogen Ⅱ are indices to reflect the degree of atrophy of the gastric mucosa, and are not specific markers to gastric cancer. Therefore, even in diseases associated with atrophy of the gastric mucosa of non-gastric cancer, may show high positive values. In addition, this method is not currently been established as alternative method for the indirect X-ray of the stomach in mass screening testing.

【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

【Reagent Composition】

1. Buffer (R1) …… Liquid
2. Latex reagent (R2) …… Liquid

(Anti-human Pepsinogen Ⅰ (mouse) monoclonal antibody sensitized latex)

【Intended use】

Measurement of Pepsinogen Ⅰ in serum or plasma sample

【Principle】

1. Principle of measurement

Antibody adsorbed latex particles and Pepsinogen Ⅰ in the sample react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of Pepsinogen Ⅰ in the sample.

2. Feature

1. Measurement principle is latex immuno turbidimetric assay.
2. It is possible to adjust to various general-purpose automatic analyzers.
3. unnecessary for preparation of reagent
4. The preprocessing of the sample (dilution of the sample) is unnecessary.

【Handling Precautions】

1. Measurement sample

Please use serum or plasma samples. The sample is stable when stored at 4℃ for 2 weeks and refrigerated (-20℃) for several months. However, please do not use sample upon repeated freezing and thawing.

2. Interfering substance etc.

The following components hardly interfered with the test result: chyle (up to formazin turbidity 2100), hemoglobin ≤500mg/dL, bilirubin F ≤20mg/dL, bilirubin C ≤20mg/dL, ascorbic acid ≤50mg/dL, and RF ≤520IU/mL.

3. Others

a. Storage reagents at (2-10℃), and the freezing preservation must be avoid.
b. Please request material separately about the adaptation example to various automated analyzers.

【Procedure】

1. Preparation of the reagents

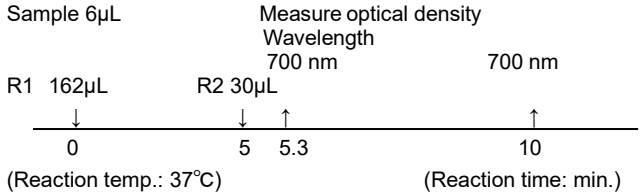
Buffer solution (R1) and Latex reagent (R2) are used as it is.

2. Stability

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10ºC and contaminations are prevented during their use.

3. Procedure

[Standard procedure]



4. Calibration

Using optional Pepsinogen Ⅰ・Ⅱ calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

【Judgment method of results】

(1) Normal reference value

Please refer to literature for values of the Pepsinogen method, i.e. serum or plasma Pepsinogen Ⅰ and Pepsinogen Ⅰ/Ⅱ ratio values. [2)3)]

Results	PG Ⅰ		PG Ⅰ/Ⅱ ratio
Strong positive	≦30 ng/mL	AND	≦2.0
Medium Positive	≦50 ng/mL	AND	≦3.0
Positive	≦70 ng/mL	AND	≦3.0
Negative	Other than the above conditions		

- The reference value may be different due to measurement conditions of the target sample, and it is recommended to be set at each laboratory.
- Clinical diagnosis based on kit measurement results, together with clinical symptoms and other test results should be evaluated by expert medical examiner.

(2)The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

【CLINICAL SIGNIFICANCE】

Pepsinogen (PG) is a precursor of the digestive enzyme pepsin produced by the stomach, produced by the gastric mucosa it is secreted in the gastric juice. It has been found that about 1% of this amount is released in the blood. PG is immunologically classified into Pepsinogen Ⅰ (PG Ⅰ) and Pepsinogen Ⅱ (PG Ⅱ). PG Ⅰ is secreted from the gastric fundic gland, while PG Ⅱ is secreted from the cardiac, pyloric and duodenal glands as well as gastric fundic gland. The amount of PG in serum reflects the active state of the stomach, and by analyzing the values of PG Ⅰ and PG Ⅰ/Ⅱ ratio more is known about the pathophysiology of the gastric mucosa, such as atrophic gastritis. In addition, as atrophy of the gastric mucosa is recognized as preceding gastric cancer lesions, the measurement of PG are increasingly been incorporated into population screening as a screening test for gastric cancer.

【PERFORMANCE】

1. ANALYTICAL PERFORMANCE

1. Sensitivity
   (a) When measured saline liquid as the sample, absorbance change (⊿OD) is below 0.0025/min, and its concentration +2SD is less than 2.5ng/mL.
   (b) When measure known concentration sample, absorbance change of Pepsinogen Ⅰ concentration 20ng/mL is between 0.0070 to 0.0555/min.
2. Accuracy
   When measured the control serum of known concentration is measured, measurement value is within ±10% of the known value.
3. Reproducibility
   When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.
4. Measurement range
   Measurement range of the Pepsinogen Ⅰ in the sample is 2.0-250 ng/mL measured by Hitach7170.

2. Correlation

Comparing this kit with a commercially available IRMA kit, as can be seen below, resulted in a good correlation for serum samples.[4]: n=106, y=1.02x + 3.71 and r=0.985.

Comparing this kit with a commercially available LIA kit, as can be seen below, resulted in a good correlation for serum samples. : n=52, y=1.01x + 0.94, and r=0.998.

Comparing this kit with a commercially available EIA kit, as can be seen below, resulted in a good correlation for plasma samples: n=58, y=1.02x + 2.31 and r=0.990.

【Attention in handling for use】

1. Attention in handling (dangerous prevention)
   (1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.
   (2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.
2. Directions
   (1) Do not use the reagents after the expiration date.
   (2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.
   (3) Please do not use the bottle and the accessory in this kit for other purposes.
   (4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.
   (5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.
   (6) Please do not use the reagent with different lot.
   (7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.
   (8) Please use the calibrator sold separately, and refers to the manual of the goods before use.
   (9) Preserve the reagent at refrigerated condition (2-10℃)and avoid the freezing.
3. Attention for Disposal
   (1) Sodium azide of 0.09w/v% is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.
   (2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.
   (3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

【Storage and validity period】

1. Storage ： 2～10℃
2. Validity period： 1 year after production
   Expiration date is displayed on the outer box and bottle labels.

【Package】

Product Name	Contents
Pepsinogen Ⅰ reagent	
Buffer (R1)	54mL ×1
Latex reagent (R2)	10mL ×1

〔Optional goods〕

(Product Name)	(Contents)
Pepsinogen Ⅰ･Ⅱ Calibrator	6 conc. x 2mL each
Pepsinogen Ⅰ･Ⅱ Control	2 concentrations ×2mL each

The indicated value is displayed on the label

【References】

1) Miki Kazumasa: Nihonijishinpo 3935: 1, 1999
2) Miki Kazumasa: Nihonnaikagakkaizasshi 89: 1942-1947, 2000
3) Masaharu Yoshihara: Clinical Gastroenterology 23: 365-371, 2008
4) Internal documents by manufacturer and distributor.

【Inquiries】

SHIMA Laboratories Co., Ltd.
Maeno-cho 3-36-3, Itabashi-ku, 174-0063 Tokyo, Japan
Tel: +81-3-3967-7277 Fax: + 81-3-3967-3241

【Manufacturing and distribution】

SHIMA Laboratories Co., Ltd.
Maeno-cho 3-36-3, Itabashi-ku, 174-0063 Tokyo, Japan