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MEASURE PG I

Reagent for determination of Pepsinogen I
Latex Immunoturbidimetric Method

2 ~ 8 °C

IVD *In vitro* Diagnostics

DO NOT freeze

18 months/block from light

Packages

R1 1×30 mL R2 1×10 mL

1. PURPOSE OF USE

In vitro determination of Pepsinogen I in blood serum or blood plasma.

2. GENERAL INSTRUCTION

1. For in vitro diagnostics use only.
2. Diagnosis should be made in a comprehensive manner, in accordance with other related test results and clinical symptoms by the doctor in attendance.
3. For guaranteed results, usage of this product must comply with the instruction in this manual.
4. For automatic analyzers, follow the instruction carefully.

Pepsinogen I and Pepsinogen II are indicators to reflect degree of atrophia of gastric mucosa, and are not specific marker to stomach cancer, therefore high positive ratio is indicated in other diseases than stomach cancer which accompany atrophia of gastric mucosa.

This method is not established as an alternative determination method to replace radiographic projection in mass-screening.

3. MATERIALS REQUIRED BUT NOT INCLUDED

- Saline 0.9 % and high grade purified water
- Micropipet and other basic laboratory equipment.
- Calibrators and Controls (separatedly sold)

4. REAGENT COMPOSITION & PREPARATION

- *Reagent R-1:* Good buffer.
- *Reagent R-2:* Anti-human Pepsinogen I antibody-conjugated latex solution
- *Calibrators & Controls (separatedly sold):* Calibrators (Level 1 – Level 6) and controls (L, H) are ready for use wthout dilution.

5. SAMPLE PREPARATION & STORAGE

- Use serum or plasma as specimens.
- Collect samples by normal method and determine while they are fresh.
- Analyze sample soon after collection. In case, it could not be analyzed soon, store samples at -20 ℃ in freezer and analyze within 1 month (avoid freeze and thaw).
- When using frozen samples, thaw them in room temperature and determine after mixing it well (transparent solution) before use.

6. MEASUREMENT PRINCIPLE

When patient sample is reacted with buffer and latex reagents, specific antigen-antibody reaction is caused by Pepsinogen I in patient samples and anti-human Pepsinogen I mouse monoclonal antibody sensitized latex, then it gives out turbidity.

Degree of turbidity is proportional to concentration of Pepsinogen I in patient samples, so concentration of Pepsinogen I in patient samples can be obtained by measuring changes of turbidity.

7. STANDARD MEASUREMENT OPERATION

	Specimen (S)	Calibrator (Std)	Blank (B)
Specimen (μL)	60	-	-
Calibrator (μL)	-	60	-
Saline (μL)	-	-	60
R-1 (μL)	1500	1500	1500
Incubate at 37 °C in 5 minutes			
R-2 (μL)	500	500	500
Mix well; incubate at 37 °C for 5 minutes; measure absorbance at 570 nm			

Note: See sample preparation for details of specimen

8. CALCULATION & UNIT CONVERSION

Calculation

- Calculate ΔAbs of specimen & standards vs blank
- Plot a calibration curve PGI (ng/mL) = f(ΔAbs)
- Calculate PGI in specimen using the curve

(doing same procedure for Controls)

Unit conversion

N/A

9. PERFORMANCE & CORRELATION TEST

Performance

- *Sensitivity:* Absorbance was less than 0.02 at 570 nm when purified water was used as sample, and change

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around 0.1 ~ 0.5 in 5 minutes when standard solution of PGI of 100 ng/mL was used as sample.

- *Specificity:* The accuracy is within ±10.0%.
- *Reproducibility:* CV value < 10.0%.
- *Measuring range:* 10 ~ 200 ng/mL

Correlation test

Company A (same principle)

Regression equation: Y = 1.0264X + 5.9878 (n = 69)

Correlation coefficient: R = 0.985

Company B (different principle)

Regression equation: Y = 1.0020X + 0.2663 (n = 54)

Correlation coefficient: R = 0.997

(Y: Value obtained from using UMA's reagent)

- *Between Serum and Plasma*

Regression equation: Y = 0.9969X - 0.0371 (n=54)

Correlation coefficient: R = 0.999

(Y: Serum; X: Plasma)

Reference Materials for Calibration

- N/A

10. EXPECTED VALUES

Judgment	Measured Value
	Pepsinogen I and PGI/PGII ratio
Strong Positive	below 30.0 and below 2.0
Medium positive	below 50.0 and below 3.0
Positive	below 70.0 and below 3.0

- Correct measurement results cannot be obtained in case non-specific reaction materials (heterophile antibody etc.) exist in the samples.
- Reference range should be established at each facility and judgement should base on measurement results in a comprehensive manner together with clinical symptoms and other measurement results.

11. INTERFERENCES

No influence of conjugated bilirubin, free bilirubin, hemolysis, lipemia and ascorbic acid against determination were observed by internal experiments.

12. INFORMATION FOR AUTOANALYZERS

❖ **For Hitachi Model**

Calculation Method		2-end point (fix)
Temperature		37 °C
Volume (µL)	Specimen	6.0
	R1	150
	R2	50
Wavelength (nm)	Main	570
	Sub-	-
Measurement (cycle)	Point 1	10
	Point 2	19
	Point 3	34
Calibration type		Spline
Unit		ng/mL

13. HANDLING, USAGE & DISPOSAL

Handling

1. Specimen can be potentially positive for infectious agents including hepatitis B virus and HIV. Wear glove and goggle when needed.
2. In case reagents got into skin, eye or mouth by mistake, wash it immediately with plenty of water and consult the doctor if needed.
3. If reagents are spilled, dilute with water and wipe it out. If specimen is spilled, spray 80% of alcohol over the specimen and wipe it out.

Usage

1. Store reagents under specified condition. Do not use after expiration date.
2. Do not use the container and auxiliaries included in this kit for other purposes.
3. Do not mix reagents of different lot for use.
4. Do not add to the reagent being used even if it is the same lot number.

Disposal

1. All specimens, as well as all instruments (e.g. test tubes) that come in contact with the specimens, must be treated by the following methods:

・Sterilize with an autoclave, subjecting them to high pressure saturated steam at 121 °C for more than 20 minutes. Do not process waste containing sodium hypochlorite solution with an autoclave.

・Immerse at least one hour in sodium hypochlorite solution (active chloride concentration of over 1000 ppm).

2. This reagent contains sodium azide. Sodium azide can react with lead pipe and/or steel pipe and can generate explosive metal azide. Make sure to use plenty of water at disposal. Concentration of sodium azide in R-2 is 0.05%.

14. OTHER INSTRUCTIONS AND CAUTION

- Results may differ depending on the sample/reagent ratio. Adjust parameters for different analyzer.
- Prepare the calibration curve on the day of determination.