Chuangxingwell

CE

Pepsinogen I/Pepsinogen II (PGI/PGII) Combo Rapid Test Kit Package Kit

IVD

FOR IN VITRO DIAGNOSTIC USE ONLY.

INTENDED USE

This kit is suitable for quantitative detection of the concentration of pepsinogen I (PG I) / pepsinogen II (PG II) in human serum, and can be used to evaluate the function of gastric acid secreting gland cells and gastric fundus mucinous gland lesions clinically.

SUMMARY

Pepsinogen I/Pepsinogen II combination (PGI/PGII) is a good diagnostic indicator for Helicobacter pylori infection, atrophic gastritis and gastric cancer lesions.

Pepsinogen is a protease precursor secreted by the gastric mucosa and can be divided into two subtypes: PG I and PG II. PG I is secreted by the main cells of the fundus glands and cervical mucus cells, and PG II is secreted by the fundus glands, pyloric glands, and Brunner glands. Most of the synthesized PG enters the gastric cavity and is activated to pepsin under the action of gastric acid. Usually, about 1% of PG can enter the blood circulation through the gastric mucosa, and the concentration of PG in the blood reflects its secretion level.

PG I is an indicator of the function of gastric oxyntic gland cells. Increased gastric acid secretion increases PG I, decreases secretion or decreases gastric mucosal gland atrophy; PG II has a greater correlation with gastric fundus mucosal lesions (compared to gastric antral mucosa). High is related to fundus gland atrophy, gastric epithelial metaplasia or pseudopyloric gland metaplasia, and dysplasia; in the process of fundus gland mucosal atrophy, the number of principal cells secreting PG I decreases and the number of pyloric gland cells increases, resulting in PG I The /PG II ratio decreases. Therefore, the PG I/PG II ratio can be used as an indication of gastric fundic gland mucosal atrophy.

PRINCIPLE

This kit is used to detect the concentrations of pepsinogen I (PG I) and pepsinogen II (PG II) in human serum samples by dual-antibody sandwich fluorescence immunoassay and near infrared laser confocal scanning technology. The reaction solution and samples are added to the protein chip immobilized with PG I and PG II monoclonal antibodies, and incubate, form an complex of “antibody-antigen-biotin labeled antibody”. The unbound free components are moved away by cleaning, then streptavidin fluorescein is added and form a biotin avidin system. Finally, a complex of “antibody-antigen-biotin labeled antibody- avidin fluorescein” is presented on the protein chip.

On the fluorescence immunoassay analyzer (FIA), the fluorescein in the above complex is excited by laser and produce fluorescence, the fluorescence signal is received by the sensor through the optical system. The fluorescence signal is positively correlated with the antigen concentration in serum. The concentration of each antigen in the calibrator can be simulated into a dose-response standard curve against its fluorescence signal, and the concentration of PGI and PGII antigens in serum samples can be calculated through the curve equation.

Kit Components

Components Name	Quantity (Loading)	Main Components
Protein-chip integrated block	1 piece (include 48 protein chips)	PG I and PG II antibodies, silicone membrane
Wash solution	1 bottle (100ml / bottle)	Tris-HCl, Tween20
Reaction solution	1 bottle (5ml / bottle)	Biotin-labeled PG I and PG II antibodies
Calibrator 0, Calibrator 5	One bottle each, lyophilized product	PG I and PG II antigen
Control 1, Control 2	One bottle each, yophilized product	PG I and PG II antigen
Redissolve solution	1 bottle (1.5ml / bottle)	Purified water
Detection solution	1 bottle (6ml / bottle)	Streptavidin-fluorescein

Note: components in different batches of kits should not be mixed.

1. The concentration of calibrators and quality control samples varies with different batches. Please refer to the target value list for the specific concentration.
2. The calibrator is from human body fluid and can be traced to Biohit Healthcare (Hefei) Co., Ltd. pepsinogen I test kit (ELISA) and pepsinogen II test kit (ELISA).
3. The quality control sample is from human body fluid.

STORAGE AND STABILITY

The unopened kit should be stored at the temperature of 2 ℃ ~8 ℃ and is valid for 12 months. Each component of the kit is a disposable product. Please use it immediately after opening the bottle. The calibrator and quality control samples shall be used immediately after re dissolution.

SPECIMEN COLLECTION

1. The sample is the serum naturally separated out after venous blood collection, and the volume of serum is not less than 100 μl; the person to be sampled should be fasting.
2. After blood sample collection, do not add anticoagulant, and place it in a clean and dry test tube for 1 hour, centrifuge (2000 rpm × 5min), suck out the serum.
3. Serum samples should be detected as soon as possible, if not used immediately, they can be stored for 7 days at the temperature of 2-8 ℃, or stored for 1 year at the temperature of -20 ℃, repeated freezing and thawing should be avoided.
4. Hemolysis, jaundice and high rheumatoid factor samples should not be tested; the sample of blood fat should be centrifuged first (20,000 rpm × 3min), after removing the upper oil, take the lower serum for detection.
5. Samples should be free from microbial contamination.

TEST PREPARATION

1. Take out the kit and equilibrate it to room temperature in the laboratory. It can only be used after it is balanced at room temperature (18-28 ℃) for 30 minutes. If the room temperature is too low (below 18 ℃), the reaction fluid and cleaning fluid can be accelerated to room temperature (18-28 ℃) at 37 ℃.
2. **Calibration dilution:**

1) Re dissolve the calibrator 5 with 120μl of redissolve solution, shake well, and fully dissolve;
2) Re dissolve the calibrator 0 with 600μl of redissolve solution, shake well, and fully dissolve;
3) Absorb 30μl of the re dissolved calibrator 5 and dilute it with 30μl of the re dissolved calibrator 0, then obtain the calibrator 4;
4) Absorb 30μl of the calibrator 4 and dilute it with 30μl of the re dissolved calibrator 0, then obtain the calibrator 3;
5) Absorb 30μl of the calibrator 3 and dilute it with 30μl of the re dissolved calibrator 0, then obtain the calibrator 2;
6) Absorb 30μl of the calibrator 2 and dilute it with 30μl of the re dissolved calibrator 0, then obtain the calibrator 1;
7) Re dissolve the control 1 and control 2 with 100μl of complex solvent respectively, shake well, and fully dissolve.

TEST PROCEDURE

1. Unpack the protein-chip integrated block, remove the storage fluid in the chip, and pat it dry.
2. Washing: Suck 200μl of the wash solution and add it into different chip reaction holes; incubate at 37 ℃ and oscillate at 1000rpm for 2 minutes, then discard the fluid in the hole. Pat it dry. Repeat washing twice. Pat it dry.
3. Add reaction solution: 8-channel pipette is used to absorb 80μl of the reaction fluid and added it into each chip hole respectively.
4. Add calibrator and control: add 20μl of calibrator 0, calibrator 1, calibrator 2, calibrator 3, calibrator 4, calibrator 5, control 1 and control 2 into the holes marked A1 to A8 of the protein-chip integrated block board respectively.
5. Add the serum sample to be tested: Add 20 μl of serum samples to be tested in the remaining holes except A1-A8.
6. Incubation: Put the protein-chip integrated block horizontally and fix it in a constant temperature shaking table, incubate it at 37 ℃ and oscillate it at 1000rpm for 20 minutes. Discard the liquid in the hole. Pat it dry.
7. Washing: see the second step.
8. Add test solution: 8-channel pipette is used to absorb 100μl of the reaction solution and added it into each chip hole respectively.
9. Incubation: Put the protein-chip integrated block horizontally and fix it in a constant temperature shaking table, incubate it at 37 ℃ and oscillate it at 1000rpm for 5 minutes. Discard the liquid in the hole. Pat it dry.
10. Washing: see the second step.

RESULT CALCULATION

1. Put the reacted protein-chip integrated block into the FIA, and the FIA reads the fluorescence signal intensity values of PG I and PG II corresponding to each hole on the protein chip.
2. Make calibration curves for PG I and PG II respectively: Take the antigen concentration of 6 calibrators as the abscissa (X) and the fluorescence signal intensity (Sd) of the antigen as the ordinate (Y), draw the calibration curve on the rectangular coordinate (automatically drawn by the FIA and calculate the regression equation.
3. Calculate the concentration of the antigen in the sample to be tested on the corresponding calibration curve in accordance with the fluorescence signal intensity (Sd) of PG I and PG II on the chip.

INTERPRETATION OF THE TEST RESULTS

1. This product can report the concentrations of PGI and PGII in human serum;
2. The level of PGI in serum can be used to evaluate the function of gastric acid secreting gland cells. PG I ≤ 70ng/mL is the cut-off value of gastric acid secreting gland cell function. PG I <30ng/mL indicates that the function of gastric acid secreting gland cells is seriously (moderately or severely) damaged.
3. PG II>15ng/mL indicates gastric fundus mucinous gland disease.
4. If the sample signal value is higher than the upper limit signal of the detection range, the measurement result is "greater than the upper limit concentration of the detection range".

QUALITY CONTROL

The quality control sample, the calibrator and the sample to be tested should be detected simultaneously. It is suggested that each laboratory should establish its own average value and allowable error range of quality control samples. If the quality control result is not within the marked value or the range determined by the laboratory, the test result is out of control. If you need to confirm the cause, you can contact local technical support.
The “r” of each calibration curve should not be less than 0.99, otherwise the test result is invalid, and it needs to be retested or contacted with local technical support.
When the test result of the quality control sample is within the range of the marked concentration, and the correlation coefficient “r” of each calibration curve is not less than 0.99, it indicates that the product meets the quality control requirements, and the test results of each sample are valid.
[Reference interval]
PG I: 70—165ng/mL
PG II: 3—15ng/mL
It is recommended that each laboratory establish its own reference interval.

LIMITATIONS OF THE ASSAY

1. The results of this experiment are only applicable to clinical auxiliary diagnosis, and cannot be used as the only standard of clinical diagnosis. Appropriate clinical treatment should be taken in combination with clinical manifestations, medical history and other diagnostic results.
2. This product can only be used for the detection of serum samples, other sample types have not been verified.

PERFORMANCE CHARACTERISTICS

1. Limit of blank:
PG I≤1.0ng/mL; PG II≤0.5ng/mL.
2. Accuracy:
It is verified by recovery test that the recovery rate of each concentration is in the range of 85% - 115%.
3. Precision:
The intra assay imprecision is not more than 10%, and the inter assay imprecision is not more than 15%.
4. Lineity range of this product:
The linear range of PG Ⅰ is 2.5~200ng/mL, and R≥0.99.
The linear range of PG Ⅱ is 1.4~100ng/mL, and R≥0.99.

PRECAUTIONS

1. The test results of this kit are only for clinical reference, and the final diagnosis should be made by the doctor after integrating various test indicators and clinical symptoms.
2. For reasons such as methodology or antibody specificity, PG I and PG II tests on the same sample with reagents from different manufacturers may yield different results. Therefore, in the process of monitoring the concentration of PG I and PG II, the results from different reagents should not be directly compared with each other, so as to avoid wrong medical interpretation; it is suggested that the laboratory should indicate the characteristics of the reagent used in the test report. If the reagent type is changed in the series monitoring, additional continuity tests should be carried out and compared with the original reagent results in parallel to re determine the baseline value.
3. There is no known test method that can completely prove that human blood samples will not cause infection. Therefore, all samples and reaction waste should be regarded as infectious with HIV, HBV, HCV and other potentially possible viruses and microorganisms; it should be operated in strict accordance with the relevant provisions of biosafety, and appropriate protective measures should be taken during the collection, disposal, storage, mixing and testing of samples.
4. 0.1g/L bilirubin, 18g/L triglyceride and 2.5g/L hemoglobin; substances less than the above concentration will not interfere with the detection of this kit.
5. The kit should be removed from the refrigerated environment and equilibrated at room temperature (18-28℃) for 30 minutes before use. If the room temperature is too low (below 18 ℃), the reaction fluid and cleaning fluid can be accelerated to room temperature (18-28 ℃) at 37 ℃.
6. The sampler should be used in each step of sampling, and its accuracy should be checked frequently to avoid experimental errors. It is best to control the time of one-time sampling within 3 minutes. If there are a large number of samples, it is recommended to use a pipette for sampling.
7. The components contained in kits of different batches cannot be mixed.
8. This product is disposable and cannot be reused.
9. All reagents should be used within the validity period. Do not use expired products.

BIBLIOGRAPHY

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SYMBOLS

	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code		Contains Sufficient for <n> Tests
	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit		Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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