GP

CE IVD

PG I/PG II
Fast Test Kit
(Immunofluorescence Assay)

REF

IF1052 for Getein1100
IF5052 for Getein1160
IF3052 for Getein1180
IF4052 for Getein1200
IF2052 for Getein1600

Instructions for Use

INTENDED USE

PG I/PG II Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of Pepsinogen I (PG I)/Pepsinogen II (PG II) in human serum, plasma samples. This test is used as an auxiliary diagnosis of the degree of gastric mucosal atrophy. For professional and laboratory use.

SUMMARY

Pepsinogen (PG) is the precursor of pepsin, a protein polypeptide chain composed of 375 amino acids, with an average relative molecular weight of 42000D. It is divided into two subgroups according to its biochemical properties and immunogenicity. Components 1-5 have similar immunogenicity, called pepsinogen I (PG I), which is mainly secreted by the main cells of the gastric fundus gland and mucous neck cells; Components 6 and 7 are called pepsinogen II (PG II). In addition to being secreted by the main cells and mucous neck cells of the gastric fundus gland, PG II can also be produced by the mucous neck cells of the cardiac gland and pyloric gland of the gastric antrum, as well as the upper segment of the duodenum. PG I is a pointer to detect the function of gastric acid secreting gland cells. When gastric acid secretion increases, PG I increases, while secretion decreases or gastric mucosal glands atrophy, PG I decreases; PG II has a greater correlation with gastric fundus mucosal lesions (relative to gastric antrum mucosa), and its increase is related to atrophy of gastric fundus glandular tubes, gastric epithelial metaplasia or pseudopyloric glandular metaplasia, and abnormal growth; The progressive decrease of PG I/PG II ratio is related to the progress of gastric mucosal atrophy. Therefore, the combined determination of PG I and PG II ratio can play a role in "serologic biopsy" of gastric fundus gland mucosa.

PRINCIPLE

PG I/PG II Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled PG I monoclonal antibody and latex-labelled PG II monoclonal antibody binds with PG I and PG II the in sample to form a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another PG I monoclonal antibody and PG II monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PG I and PG II in sample. Fluorescent signals intensity can be analyzed by applicable device thus the PG I and PG II in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
PG I/PG II test card	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent	10*1 mL/tube	25*1 mL/tube	1 box	1 box
User manual	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 consists of:
Sample diluent contains phosphate buffer (20 mmol/L), NaN3 (< 0.1%).
Sample diluent for Getein 1200/ Getein 1600 consists of:
-Sample diluent contains phosphate buffer (20 mmol/L), NaN3 (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
-Box with pipette tips (96 tips/box),
-Mixing plate (1 piece/box).
A test card consists of: Fluorescence latex-labelled PG I monoclonal antibody and latex-labelled PG II monoclonal antibody, PG I monoclonal antibody and PG II monoclonal antibody and Goat polyclonal antibody.

Note:
1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30 ℃ with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
For the test card of Getein 1200/Getein 1600: The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
3. Sample diluent contains NaN3 (<0.1%) as a preservative. NaN3 can react with copper or lead pipes in drain lines to form explosive compounds. Dispose properly in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used on plasma and serum samples.
2. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 24 hours after collection. Stable in plasma and serum for 7 days when stored at 2~8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

CALIBRATION

Calibration: The regression equation fitting the concentration value of the working calibrator with the reaction signal value is written into the SD card in advance. Before detection, the SD card is written into the instrument, which can automatically read the calibration curve information in the SD card. During detection, the content of analyte can be calculated by substituting the obtained signal value into the regression equation.
Calibration Frequency: A new calibration is required when using a new reagent lot or a new instrument.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the user manual before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Select the corresponding mode on the analyzer according to the sample type (see the instructions of analyzer for details).

For Getein 1100:
(1) Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(3) Deliver 100 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample port “S” on the test card.
(4) Reaction time: 15 minutes. Insert the test card into Getein 1100 and press "ENT" button (click on “Start” icon for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:
(1) Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(3) Deliver 100 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample port “S” on the test card.
(4) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:
(1) Insert the test card cartridge into the analyzer, each test card cartridge for Getein 1200/Getein 1600 contains a specific SD card which can calibrate automatically.
(2) Place the sample diluent at the correct position.
(3) Place samples on sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will perform the testing and print the result automatically.

Notes:
Make sure insertion of the test card cartridge and the sample are correct and complete.

RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/ Getein1180/Getein1200/ Getein1600.
Others: Measuring range of the Pepsinogen I and Pepsinogen II Fast Test Kit is
PG I 1.0-200.0 ng/ml and PG II 1.0 ~ 100.0 ng/mL. Samples initially outside the measuring range may be diluted with 1% bovine serum albumin, measuring range can be up to PG I 1000 ng/mL and PG II 500 ng/mL through dilution.

PERFORMANCE CHARACTERISTICS

1. Measuring Range
   PG I: 1.0~200.0 ng/ml; PG II: 1.0 ~ 100.0 ng/mL.
2. Limit of Detection
   PG I ≤1.0 ng/mL; PG II ≤1.0 ng/mL.
3. Within-Run Precision ≤10%

4. Between-Run Precision ≤15%

LIMITATIONS

1. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical examination, medical history and other examination results.
2. Do not use the test card if the foil pouch or the cartridge is damaged.
3. Do not open pouches until performing the test.
4. Getein 1200/ Getein 1600 test card cartridge, keep dry and put back to the foil bag for 7 days if not used up.
5. Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all specimens cannot be guaranteed.
6. Triglyceride and bilirubin in the sample may interfere with the test results, and the maximum allowable concentrations are 18 g/L and 0.1 g/L respectively.

EXPECTED VALUE

PG I less than 70ng/ml and PG I / PG II ratio less than 3.0 are the cut-off values of the highest positive rate of gastric fundus gland mucosal atrophy, which are 80% specific for non-gastric fundus gland mucosal atrophy. Therefore, we suggest that PG I ≥70.0 ng/ml or PG I / PG II ≥ 3.0 as the reference interval of normal human serum.
Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

REFERENCES

1. Kikuchi S, Wada O, Miki K, et al. Serum pepsinogen as a new marker for gastric carcinoma among young adults. Cancer 1994; 73: 2695- 2702.
2. Suzuki H, Masaoka T, Hosoda H, et al. Plasma ghrelin concentration correlates with the levels of serum pepsinogen I and pepsinogen I/II ratio--a possible novel and non-invasive marker for gastric atrophy. [J]. Hepato-gastroenterology, 2004, 51(59):1249-1254.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PG I/PG II Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for using PG I/PG II Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Document no.: WIF91-S-02
Effective date: 2023.04.11

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054