



# PCT

## Fast Test Kit

### (Immunofluorescence Assay)

#### Instructions for Use

#### INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in human serum, plasma and whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of bacterial infection, trauma or shock. For professional and laboratory use only.

#### SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.

Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.

PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

#### PRINCIPLE

PCT 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 labelled PCT antibody binds with the PCT in sample and forms 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 PCT antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT in sample. Fluorescent signals intensity can be analyzed by applicable device thus the PCT in sample be detected quantitatively.

#### CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2*12 T/kit	2*24 T/kit	2*48 T/kit
PCT test card	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Whole blood buffer	1*2 mL/tube	1*2 mL/tube	/	/	/	/	/
Sample diluent	/	/	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

- 1) Main key components in the kit  
- Fluorescence labelled PCT antibody and PCT antibody.
- 2) Main key components in Whole blood buffer for Getein 1100/Getein 1160/Getein 1180  
- Phosphate buffer, Na<sub>2</sub> (< 0.1%).
- 3) Main key components in Sample diluent for Getein 1150  
- Phosphate buffer, Na<sub>2</sub> (< 0.1%).
- 4) Main key components in Sample diluent for Getein 1600/Getein 1200  
- Phosphate buffer, Na<sub>2</sub> (< 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).

#### Note:

1. The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.

3. Do not mix or interchange different batches of kits.

#### APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer  
Getein 1150 Immunofluorescence Quantitative Analyzer  
Getein 1160 Immunofluorescence Quantitative Analyzer  
Getein 1180 Immunofluorescence Quantitative Analyzer  
Getein 1200 Immunofluorescence Quantitative Analyzer  
Getein 1600 Immunofluorescence Quantitative Analyzer

#### STORAGE AND STABILITY

##### Realtime stability:

Store the kit at 4–30°C 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 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

#### PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Do not reuse the test card and disposable pipet.
6. 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.
7. It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

#### SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma and whole blood can be used as samples in the assay.

2. Heparin and sodium citrate can be used as the anticoagulant for plasma and sodium citrate can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.
3. Suggest using serum or plasma for better results.
4. Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
5. Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
6. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

#### TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

##### For Getein 1100:

- 1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- 4) Deliver **100 µL** of sample into the sample well on the test card using disposable pipet or pipette (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
- 5) **Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). 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. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).

- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 µL** of sample into the sample well on the test card using disposable pipet or pipette (for whole blood sample, one drop of whole blood buffer must be added after loading **100 µL** sample on the test card).
- 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 1150:**

- Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- Deliver **20 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 well on the test card.
- Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

#### **For Getein 1200/Getein 1600:**

- Place the reagent cartridge in the cartridge zone. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

#### **LIMITATIONS**

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and

- symptoms.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

- Measuring range of the PCT is 0.05–50.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ratio should be less than 5 times.

#### **EXPECTED VALUE**

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> percentile of the concentration for PCT is 0.10 ng/ml. (The probability that value of a normal person below 0.10 ng/ml is 99%.) The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning<sup>[4]</sup>:

PCT concentration	Clinical significance
< 0.50 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.50 and < 2.00 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.00 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

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.

#### **PERFORMANCE CHARACTERISTICS**

Measuring Range	0.05–50.00 ng/mL
Limit of Detection	≤ 0.05 ng/mL
Within-Run Precision	≤ 10%
Between-Lot Precision	≤ 15%

#### **REFERENCES**

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- Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
- Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
- Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
- EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- 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 PCT Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for using PCT Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF1007-10T	Getein 1100	10 T/kit
IF1007	Getein 1100	25 T/kit
IF8007-10T	Getein 1150	10 T/kit
IF8007	Getein 1150	25 T/kit
IF5007-10T	Getein 1160	10 T/kit
IF5007	Getein 1160	25 T/kit
IF3007-10T	Getein 1180	10 T/kit
IF3007	Getein 1180	25 T/kit
IF4007-24T	Getein 1200	2×12 T/kit
IF4007	Getein 1200	2×24 T/kit
IF4007-96T	Getein 1200	2×48 T/kit
IF2007-24T	Getein 1600	2×12 T/kit
IF2007	Getein 1600	2×24 T/kit
IF2007-96T	Getein 1600	2×48 T/kit