



# PCT Fast Test Kit (Immunofluorescence Assay)

## Instructions for use



IF1007 for Getein 1100  
IF5007 for Getein 1160  
IF3007 for Getein 1180

## INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in human serum, plasma, whole blood and fingertip blood samples. 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.

## 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 based on the lateral flow immunoassay technology in a sandwich design. Once the sample is applied to the test strip, the fluorescence latex-labelled PCT monoclonal antibody will bind with PCT in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by another PCT monoclonal antibody.

Fluorescent signals intensity can be analyzed by applicable device thus the amount of PCT in the sample can be detected quantitatively.

## CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
PCT test card*	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent**	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

\* PCT test card

A test card main consists of: Fluorescence latex-labelled PCT monoclonal antibody, PCT monoclonal antibody and polyclonal IgG antibody.

\*\* Sample diluent

Sample diluent main contained in each tube: Phosphate buffer (20 mmol/L), NaN3 (<0.1%).

**Note:**

- 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".
- Do not mix or interchange different batches of kits.

## APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1180 Immunofluorescence Quantitative Analyzer

Getein1160 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

Store the test kit at 4-30°C with a valid period of 24 months.

Use the test card for Getein 1100/Getein 1160/Getein 1180 within one hour once the foil pouch is opened.

## PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform

the test.

- Do not reuse the test card.
- Do not reuse the disposable pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow instructions for use to ensure proper test performance.

## SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum, plasma, whole blood and fingertip blood samples**. **Heparin, sodium citrate** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum or plasma for better results.
- It is recommended to test the sample within 4 hours after collection. Stable in plasma for 5 days when stored at 2-8°C and 6 months when stored at -20°C. Stable in whole blood and fingertip blood for 3 days when stored at 2-8°C.
- Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

## TEST PROCEDURE

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

For Getein 1100:

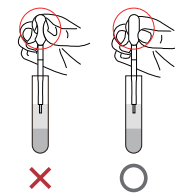
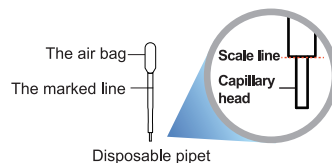
- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Using disposable pipet or pipette, deliver **20 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- 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.

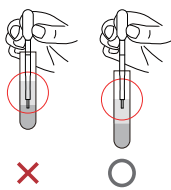
For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- 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 immediately before use and put the test card on a clean table, horizontally placed.
- Using disposable pipet or pipette, deliver **20 µL** of sample into one tube of sample diluent, mix thoroughly. Then drop **100 µL** of sample mixture into the sample well 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 displayed automatically.

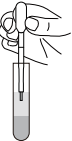
**For using the disposable pipet:**




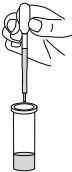
**Note1:** Do not depress the air bag of the disposable pipet with your finger during sampling.

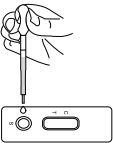


**Note 2:** The capillary head of the disposable pipette touches the sample level gently and draws the sample automatically.

a.  Gently hold the air bag of the disposable pipet and insert the disposable pipet into the sample collection tube until the **scale line** reaches the liquid level. The sample will be sucked into the disposable pipette by capillary action.

b.  Insert the disposable pipette into the sample diluent. Squeeze the air bag 8 to 10 times to ensure the sample is fully mixed with the sample diluent.

c.  Squeeze the air bag, suck the sample mixed solution to the **marked line** on the disposable pipette.

d.  Add all the sucked sample vertically to the sampling area of test card.

#### Notes:

- It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the test card and the sample insertion are correct and complete.

## TEST RESULTS

Getein 1100/Getein 1160/Getein 1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180.

Others: 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/SC-CM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning (4).

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.

It is recommended that each laboratory establish its own expected values for the population it serves.

## PERFORMANCE CHARACTERISTICS

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

## LIMITATIONS















- Bilirubin, triglyceride and hemoglobin in the sample may interfere with the test results, and the maximum allowable concentrations are 0.2 g/L, 10 g/L and 5 g/L respectively.
- The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

## REFERENCES

- Bald C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85–90.
- 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 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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult <i>instructions for use</i>
	Catalogue number		Caution

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

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