PCT Rapid Quantitative Test

CE IVD

INTENDED USE

The Biotime PCT Rapid Quantitative Test is intended to quantify the concentration of PCT in human serum, plasma or whole blood on Biotime FIA Analyzer (Semi-automatic / Automatic) by fluorescent immunoassay. The test is used as an aid detection of infection.
-Fluorescence immunoassay
-Infection
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Procalcitonin (PCT) is a precursor peptide with the molar of 13000 Dalton, that consists of 116 amino acids, free of activity compared to the calcitonin sample. Its molecule is made up of calcitonin, katacalcin and an end of a fragment including 57 amino acids. It is stable in vivo, with half-life period of 25-30 hours. It is produced by liver, as well as unicellular organ, spleen and lung. When infected by severe systemic bacteria, fungus, PCT is ectopic generated[1-4].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the PCT in the sample and the mouse anti-PCT monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with PCT specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of PCT in human serum, plasma or whole blood.
The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of PCT in human serum, plasma or whole blood.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use.
4. Once opening, the reagent should be used within the specified time to avoid detection failure due to moisture absorption.
5. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
6. Lot number of buffers and test cartridges must be matched.
7. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided
The following components are included in the PCT Rapid Quantitative Test.
Specification and Component

1. For type A reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT2301	25 tests/kit	25 tubes/kit	1 piece/kit	1 copy/kit

2. For type B reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT0203501	25 tests/kit	1 panel/25 tests	1 piece/kit	1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer

Applied information	Biotime FIA Analyzer	Applicable model
For type A reagent	Semi-automatic	BIOT-YG-I, FLI-100, FLI-600, FLI-1200
For type B reagent	Automatic	FLI-4000

2. Transfer Pipette Set (range 10~100μL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. For Type A reagent: Test cartridge should be used within 30 min after opening the pouch. For Type B reagent: After opening the kit, it should be exposed to the air for no more than 24 hours under the conditions of 10-30 ℃ and 30%-90% relative humidity. It is recommended to use the original self-sealing pouch to seal the unused test cartridge and use it within 7 days. And the sample buffer should be ready for use.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with human whole blood, plasma or serum specimen.
2. The specimen collection container should be heparin anticoagulant tube for whole blood or plasma and immune tube or pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the serum or plasma specimen can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 7 days, or at -20℃ for no more than 6 months. If the whole blood specimen can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 7 days. Specimen must be recovered to the room temperature before tests.
4. Separate the plasma or serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA Analyzers for details.
The test should be operated at room temperature (~25℃).

For Type A reagent

Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
For serum or plasma: Take 50uL of serum or plasma with a transfer pipette and add it into the buffer tube.
For whole blood: Take 80uL of whole blood with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 15 minutes.

For Type B reagent

Step 1: Preparation

Check the lot number. Tear the aluminum foil bag, take out the test cartridge and buffer, and put it into the analyzer card slot.

Step 2: Sampling

For Serum or plasma samples, after put the samples to be tested into the analyzer, the analyzer automatically absorbs 50μL samples.

For whole blood sample, after put the sample to be tested into the analyzer, the analyzer automatically absorbs 80μL sample;

Step 3: Mixing

The instrument automatically adds the sample into the sample buffer, and then fully mixed.

Step 4: Loading

The instrument automatically absorbs 80μL of the above mixed solution into the detection hole of the test cartridge, and moves it to the incubator;

Step 5: Testing

After sample mixture addition, the test cartridge reacts in the incubation tank for 15min, and the analyzer reads the result;

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value: <0.5ng/mL
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum, plasma or whole blood.
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[5-6].
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Test cartridges from same batch were tested with PCT control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15%.
Assay Range: 0.1-100.0ng/mL
The Lowest Detection Limit: 0.1ng/mL
Linearity
A serial concentration of PCT controls at 0.1-100.0ng/mL were tested, the Correlation Coefficient (R) is≥0.9900.
Precision
Intra-Lot Precision
Intra-lot precision was determined by testing of PCT reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
Inter-Lot Precision
Inter-lot precision was determined by testing of PCT reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.
Specificity:

Specific antigen	Concentration	PCT Test result
albumin	100g/L	<0.3ng/mL
human Calcitonin	100ng/mL	<0.3ng/mL
ca inhibitory peptides	10ng/mL	<0.3ng/mL
α-CGRP	10μg/mL	<0.3ng/mL
β-CGRP	10μg/mL	<0.3ng/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 8℃	Store at 2-8℃
	Do not re-use	2℃ 30℃	Store at 2-30℃
EC REP	Authorized representative in the European Community/European Union	CE	CE mark

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