

# Procalcitonin FS\*

## Order Information

Cat. No.                      Kit size  
1 7318 99 10 930      R1 2 x 18 mL      +      R2 2 x 6 mL

## Intended Use

Diagnostic reagent for quantitative in vitro determination of procalcitonin (PCT) in human serum or heparin plasma on automated photometric systems.

## Summary

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host immune response to infection. It is a global health concern and a leading cause of death worldwide, affecting an estimate of 48.9 million people each year [1-3]. Early diagnosis and treatment of sepsis still remains a big challenge in the intensive care units. PCT, the thyroid precursor of calcitonin, is a 116 amino acid polypeptide with a molecular weight of approximately 13 kDa. Under physiological conditions, PCT is exclusively synthesized by thyroid C cells and undergoes successive cleavages into three fragments, N-terminus, calcitonin and katacalcin [3-8]. PCT serum levels in healthy individuals are very low (< 0.05 ng/mL). In response to microbial systemic infections and sepsis, PCT is ubiquitously expressed in multiple tissues via stimulation by inflammatory cytokines or bacterial endotoxins and may increase up to 1000 ng/mL [5-8]. However, in order to correctly interpret PCT results, they should be placed into clinical context. Clinical findings, evaluation of severity of illness and of patient's characteristics should be taken into account. Thus, decisions should not be based solely on PCT serum levels [9].

## Method

Particle enhanced immunoturbidimetric test

Determination of PCT concentration by photometric measurement of antigen antibody reaction between antibodies against human PCT bound to polystyrene particles and PCT present in the sample.

## Reagents

### Components and Concentrations

R1: TRIS                                      pH 6.5                      0.1 mol/L  
R2: TRIS                                      pH 9.0                      0.1 mol/L  
Polyclonal antibodies (goat) against human PCT covalently bound to polystyrene particles.

## Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The in-use stability of the reagent is 24 months.

## Warnings and Precautions

1. Reagent 1 contains sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [10].
5. In rare cases, implausibly high results may occur. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
7. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
8. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For

diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

9. For professional use only.

## Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

## Reagent Preparation

The reagents are ready to use.

## Materials Required

General laboratory equipment

## Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [11,12]:

24 hours	at	20 – 25°C
5 days	at	2 – 8°C
14 days	at	-20°C

Only freeze once. Discard contaminated specimens.

## Assay Procedure

### Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	658 nm
Temperature	37°C
Measurement	Endpoint
Sample/calibrator	7.5 µL
Reagent 1	90 µL
Reagent 2	30 µL
Addition Reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 23/24 (340 s/ 354 s)
Absorbance 2	Cycle 41/42 (586 s/ 600 s)
Calibration	Spline

## Calculation

The PCT concentration of unknown samples is derived from the calibration curve using an appropriate mathematical model such as RCM or spline. The calibration curve is obtained with six calibrators at different levels, including a matrix-based zero-value.

## Calibrators and Controls

DiaSys TruCal PCT is recommended for calibration. Calibrator values have been made traceable to a commercially available test on Roche cobas e 411. Use DiaSys TruLab PCT Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal PCT	1 7310 99 10 082	6 x 1 mL
TruLab PCT Level 1	5 9970 99 10 046	3 x 1 mL
TruLab PCT Level 2	5 9980 99 10 046	3 x 1 mL

## Performance Characteristics

### Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range from 0.27 ng/mL up to 50 ng/mL, depending on the concentration of the highest calibrator.  
Linearity < 0.5 ng/mL is given with  $\pm 0.1$  ng/mL, between 0.5 ng/mL to 5 ng/mL within  $\pm 20\%$ , at > 5 ng/mL within  $\pm 10\%$ .  
When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Limit of detection**	0.27 ng/mL
Limit of quantitation**	0.27 ng/mL
No prozone effect up to 1000 ng/mL.	

Interference by	Interferences $\leq 15\%$ up to	Analyte concentration [ng/mL]
<b>Ascorbic acid</b>	151 mg/dL	0.605
	151 mg/dL	1.92
<b><math>\alpha</math>-CGRP</b>	12 $\mu$ g/mL	0.584
	12 $\mu$ g/mL	1.74
<b>Azithromycin</b>	1.44 mg/dL	0.623
	1.44 mg/dL	1.67
<b><math>\beta</math>-CGRP</b>	12 $\mu$ g/mL	0.632
	12 $\mu$ g/mL	1.79
<b>Bilirubin (conjugated)</b>	72.5 mg/dL	0.617
	72.5 mg/dL	1.97
<b>Bilirubin (unconjugated)</b>	71.4 mg/dL	0.537
	71.4 mg/dL	1.67
<b>Calcitonin</b>	12 ng/mL	0.603

	12 ng/mL	1.87
<b>Cefotaxime</b>	189 mg/dL	0.609
	189 mg/dL	1.93
<b>Cromolyn</b>	28.8 mg/L	0.623
	28.8 mg/L	1.90
<b>Dobutamine</b>	22.9 $\mu$ g/mL	0.615
	22.9 $\mu$ g/mL	1.94
<b>Dopamine</b>	27.3 mg/dL	0.621
	27.3 mg/dL	1.94
<b>Doxycycline</b>	6.61 mg/dL	0.605
	6.61 mg/dL	1.96
<b>Enoxaparin</b>	24000 U/L	0.638
	24000 U/L	1.82
<b>Ethanol</b>	720 mg/dL	0.642
	720 mg/dL	1.83
<b>Furosemide</b>	4.2 mg/dL	0.656
	4.2 mg/dL	1.98
<b>Hemolysis</b>	1200 mg/dL	0.588
	1200 mg/dL	1.86
<b>Ibuprofen</b>	63.1 mg/dL	0.574
	63.1 mg/dL	1.98
<b>Imipenem</b>	2.52 mg/mL	0.626
	2.52 mg/mL	1.86
<b>Katacalcin</b>	6 ng/mL	0.655
	12 ng/mL	2.09
<b>Lipemia (triglycerides)</b>	1910 mg/dL	0.653
	1910 mg/dL	1.62
<b>Noradrenalin</b>	4.2 $\mu$ g/mL	0.600
	4.2 $\mu$ g/mL	1.76
<b>Pantoprazole</b>	4.32 mg/dL	0.657
	4.32 mg/dL	1.94
<b>Rheumatoid factor</b>	1020 IU/mL	0.560
	1020 IU/mL	1.57
<b>Salmeterol Xinafoate</b>	104 ng/mL	0.604
	104 ng/mL	1.77
<b>Scopolamine-N-butyl bromide</b>	72 mg/L	0.551
	72 mg/L	1.68
<b>Vancomycin</b>	3.78 mg/mL	0.642
	3.78 mg/mL	1.98

N-Terminus interferes.

For further information on interfering substances, refer to Young DS [13,14].

### Precision

Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [ng/mL]	0.602	1.96	9.43
CV [%]	5.11	2.96	2.49
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [ng/mL]	0.566	2.23	10.8
CV [%]	5.94	2.90	2.04
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [ng/mL]	0.593	2.09	10.3
CV [%]	6.43	3.34	4.11

Method comparison (n=120)	
Test x	Competitor Procalcitonin (VIDAS®)
Test y	DiaSys Procalcitonin FS (BioMajesty®JCA-BM6010/C)
Slope	1.08
Intercept	0.092 ng/mL
Coefficient of correlation	0.991

\*\* according to CLSI document EP5-A3, Vol. 34, No. 13

\*\* according to CLSI document EP17-A2, Vol. 32, No. 8

## Reference Range

Serum and plasma [15,16]:

< 0.5 ng/mL	Systemic infection (sepsis) is unlikely. Low levels do not exclude an infection, because localized infections (without systemic signs) may be associated with such low levels.
≥ 0.5 and < 2 ng/mL	Systemic infection (sepsis) is possible. Patient should be closely monitored.
≥ 2 and < 10 ng/mL	Represent a high risk of severe sepsis and/or septic shock.
≥ 10 ng/mL	Severe sepsis or septic shock, almost exclusively due to severe bacterial infection.

**Note:** PCT levels may be elevated independently of bacterial infection in neonates (< first 3 days of life, physiological elevation) [16-18]. Increased levels of PCT may also occur in patients with special medical conditions eg. polytrauma, major surgery and severe burns [6,7,15,16].

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature

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