BioMajesty®

Procalcitonin FS*

Order Information

Cat. No.	Kit size
1 7318 99 10 966	320 (R1: 2 x 160, R2: 2 x 160)

Intended Use

Diagnostic reagent for quantitative in vitro determination of procalcitonin (PCT) in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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 open-vial stability of the reagent is 24 months until expiry date.

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 case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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. The bottles are placed directly into the reagent rotor.

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.

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

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 ± 0.1 ng/mL, between 0.5 ng/mL to 5 ng/mL within ± 20%, at > 5 ng/mL within ± 10%.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.27 ng/mL
Limit of quantitation**	0.27 ng/mL
No prozone effect up to 1000 ng/mL.	
Onboard stability (with chimney)	8 weeks
Calibration stability (with chimney)	4 weeks

Interference by	**Interferences ≤ 15% up to**	**Analyte concentration [ng/mL]**
Ascorbic acid	151 mg/dL	0.605
	151 mg/dL	1.92
α-CGRP	12 µg/mL	0.584
	12 µg/mL	1.74
Azithromycin	1.44 mg/dL	0.623
	1.44 mg/dL	1.67
β-CGRP	12 µg/mL	0.632
	12 µg/mL	1.79
Bilirubin (conjugated)	72.5 mg/dL	0.617

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	72.5 mg/dL	1.97
Bilirubin (unconjugated)	71.4 mg/dL	0.537
	71.4 mg/dL	1.67
Calcitonin	12 ng/mL	0.603
	12 ng/mL	1.87
Cefotaxime	189 mg/dL	0.609
	189 mg/dL	1.93
Cromolyn	28.8 mg/L	0.623
	28.8 mg/L	1.90
Dobutamine	22.9 µg/mL	0.615
	22.9 µg/mL	1.94
Dopamine	27.3 mg/dL	0.621
	27.3 mg/dL	1.94
Doxycycline	6.61 mg/dL	0.605
	6.61 mg/dL	1.96
Enoxaparin	24000 U/L	0.638
	24000 U/L	1.82
Ethanol	720 mg/dL	0.642
	720 mg/dL	1.83
Furosemide	4.2 mg/dL	0.656
	4.2 mg/dL	1.98
Hemolysis	1200 mg/dL	0.588
	1200 mg/dL	1.86
Ibuprofen	63.1 mg/dL	0.574
	63.1 mg/dL	1.98
Imipenem	2.52 mg/mL	0.626
	2.52 mg/mL	1.86
Katacalcin	6 ng/mL	0.655
	12 ng/mL	2.09
Lipemia (triglycerides)	1910 mg/dL	0.653
	1910 mg/dL	1.62
Noradrenalin	4.2 µg/mL	0.600
	4.2 µg/mL	1.76
Pantoprazole	4.32 mg/dL	0.657
	4.32 mg/dL	1.94
Rheumatoid factor	1020 IU/mL	0.560
	1020 IU/mL	1.57
Salmeterol Xinafoate	104 ng/mL	0.604
	104 ng/mL	1.77
Scopolamine-N-butyl bromide	72 mg/L	0.551
	72 mg/L	1.68
Vancomycin	3.78 mg/mL	0.642
	3.78 mg/mL	1.98
N-Terminus interferes.		
For further information on interfering substances, refer to the literature [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 EP05-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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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

BioMajesty

Procalcitonin FS

Chemistry code 10 731

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	90
R2e volume	0
R2 volume	30
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	7.5
Sample vol (U)	7.5
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	23
S-DET.P.r	24
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	PCT
Digits	2
M-wave L.	658
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	3
Factor	3
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	7.5	7.5
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Spline	**Axis Conv**	No conv
Blank	Blank is 0	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	7.5	No dil	0	0	0	9.999	-9.999
1	#	7.5	No dil	0	0	0	9.999	-9.999
2	#	7.5	No dil	0	0	0	9.999	-9.999
3	#	7.5	No dil	0	0	0	9.999	-9.999
4	#	7.5	No dil	0	0	0	9.999	-9.999
5	#	7.5	No dil	0	0	0	9.999	-9.999

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