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

Reagent for quantitative in vitro determination of procalcitonin (PCT) in serum or plasma on 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]

Method

Particle enhanced immunoturbidimetric test.

Determination of procalcitonin concentration by photometric measurement of antigen antibody reaction between antibodies against human procalcitonin bound to polystyrene particles and procalcitonin 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 Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light.

Warnings and Precautions

1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [9].
4. Please refer to the safety data sheets 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.
5. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagent is ready to use.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [10, 11]:

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

Applications for automated systems are available on request.

Basic parameter for cobas c 501

Wavelength	660 nm
Temperature	37°C
Measurement	2 point end
Sample/calibrator	10 µL
Reagent 1	120 µL
Reagent 2	40 µL
Addition Reagent 2	Cycle 35 (~300 s)
Absorbance 1	Cycle 41 (~350 s)
Absorbance 2	Cycle 70 (~600 s)
Calibration	RCM

Note: For adapted procedures, calculate volumes of sample, calibrator and reagents appropriately and keep exactly to timing.

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.

Stability of calibration: 4 weeks

Calibrators and Controls

DiaSys TruCal PCT is recommended for calibration. TruCal PCT values have been made traceable in a method comparison of Procalcitonin FS versus a commercially available test on Roche cobas e 411. Use DiaSys TruLab PCT for internal quality control. 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 cobas c 501

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range from 0.2 up to 50 ng/mL, depending on the concentration of the highest calibrator. 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**	0.2 ng/mL
No prozone effect up to	1000 ng/mL

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	150 mg/dL
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Hemoglobin	1000 mg/dL
Lipemia (Triglycerides)	1500 mg/dL
Rheumatoid factor	1000 IU/mL
α-CGRP (human)	10 µg/mL
β-CGRP (human)	10 µg/mL
Calcitonin (human)	20 ng/mL
Cefotaxime	180 mg/dL
Dobutamine	22.4 µg/mL
Dopamine	26 mg/dL
Furosemide	4 mg/dL
Imipenem	0.5 mg/mL
Noradrenalin (Norepinephrine)	4 µg/mL
Vancomycin	3 mg/mL
For further information on interfering substances refer to Young DS [12].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [ng/mL]	0.446	1.98	9.73
CV [%]	6.53	4.17	3.74
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [ng/mL]	0.500	1.87	9.48
CV [%]	7.34	5.00	3.56

Method comparison (n=148)	
Test x	Competitor Procalcitonin
Test y	DiaSys Procalcitonin FS
Slope	0.919
Intercept	0.041 ng/mL
Coefficient of correlation	0.983

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

Reference Range

As follows [13, 14]:

Serum and plasma:

< 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) [14-16]. Increased levels of PCT may also occur in patients with special medical conditions eg. polytrauma, major surgery and severe burns. [6, 7, 13, 14]

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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DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
www.diasys-diagnostics.com

* Fluid Stable