respons®920

Procalcitonin FS*

Order Information

Cat. No.	Kit size
1 7318 99 10 925	Σ 120 (1 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of procalcitonin (PCT) in human serum or heparin plasma on automated respons®920.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
7. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
8. 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.
9. 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.
10. 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 0.26 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**	0.26 ng/mL
Limit of quantitation**	0.26 ng/mL
No prozone effect up to 1000 ng/mL.	
Onboard stability (without chimney)	20 days
Calibration stability (without chimney)	1 week
Onboard stability (with chimney)	2 weeks
Calibration stability (with chimney)	2 weeks

Interference by	Interferences ≤ 15% up to	Analyte concentration [ng/mL]
Ascorbic acid	151 mg/dL	0.607
	151 mg/dL	1.83
α-CGRP	12 µg/mL	0.636
	12 µg/mL	1.77
Azithromycin	1.44 mg/dL	0.600
	1.44 mg/dL	1.75
β-CGRP	12 µg/mL	0.671
	12 µg/mL	1.90
Bilirubin (conjugated)	72.5 mg/dL	0.668
	72.5 mg/dL	1.88
Bilirubin (unconjugated)	71.4 mg/dL	0.582
	71.4 mg/dL	1.60
Calcitonin	12 ng/mL	0.586
	12 ng/mL	1.82
Cefotaxime	189 mg/dL	0.607
	189 mg/dL	1.85
Cromolyn	28.8 mg/L	0.665
	28.8 mg/L	1.88
Dobutamine	22.9 µg/mL	0.641
	22.9 µg/mL	1.92
Dopamine	27.3 mg/dL	0.620
	27.3 mg/dL	1.82
Doxycycline	6.61 mg/dL	0.611
	6.61 mg/dL	1.86
Enoxaparin	24000 U/L	0.682
	24000 U/L	1.90
Ethanol	720 mg/dL	0.662
	720 mg/dL	1.75
Furosemide	4.2 mg/dL	0.668
	4.2 mg/dL	1.88
Hemolysis	1200 mg/dL	0.647
	1200 mg/dL	1.83
Ibuprofen	63.1 mg/dL	0.599
	63.1 mg/dL	1.99
Imipenem	2.52 mg/mL	0.627
	2.52 mg/mL	1.77
Katacalcin	10.8 ng/mL	0.724
	12 ng/mL	1.95
Lipemia (triglycerides)	1900 mg/dL	0.630
	1900 mg/dL	1.48
Noradrenalin	4.2 µg/mL	0.606
	4.2 µg/mL	1.76
Pantoprazole	4.32 mg/dL	0.638
	4.32 mg/dL	1.93
Rheumatoid factor	1020 IU/mL	0.625
	1020 IU/mL	1.57
Salmeterol Xinafoate	104 ng/mL	0.667
	104 ng/mL	1.89
Scopolamine-N-butyl bromide	72 mg/L	0.600
	72 mg/L	1.68
Vancomycin	3.78 mg/mL	0.616
	3.78 mg/mL	1.93
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]	0.487	1.75	8.93
CV [%]	4.57	4.52	2.63
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [ng/mL]	0.581	2.17	10.1
CV [%]	6.95	3.78	3.92
Reproducibility (n=75, no. of instruments=3)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [ng/mL]	0.572	2.03	10.6
CV [%]	18.8	7.39	3.24

Method comparison (n=120)	
Test x	Competitor Procalcitonin (VIDAS®)
Test y	DiaSys Procalcitonin FS (respons®920)
Slope	1.06
Intercept	0.103 ng/mL
Coefficient of correlation	0.989

** 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

1. Rudd KE et al. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study, The Lancet 2020; 395 (10219): 200-211.
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Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

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* Fluid Stable

respons®920

Procalcitonin FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	PCT				Auto Rerun		☐
Report Name	:	Procalcitonin				Online Calibration		☐
Unit	:	ng/mL	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	660	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline	Reagent R1	:	PCT R1
M1 Start	:	20	M1 End	:	20	Reagent R2	:	PCT R2
M2 Start	:	34	M2 End	:	36			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator 1		*
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 2		*
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 3		*
Technical Minimum	:	0.0000	Technical Maximum	:	0.0000	Calibrator 4		*
Y = aX + b a=	:	1.0000	b=	:	0.0000	Calibrator 5		*

* Enter calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	PCT				
Sample Type	:	Serum				

Sample Volumes

Normal	:	12.00 µL	Dilution Ratio	:	1 X
Increase	:	0.00 µL	Dilution Ratio	:	0 X
Decrease	:	0.00 µL	Dilution Ratio	:	0 X
Standard Volume	:	12.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	144 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	48 µL	R2 Stirrer Speed	:	Medium

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	PCT		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (ng/mL)	Upper Limit (ng/mL)
Normal	:	0.00	0.50
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other