

QUANTITATIVE DETERMINATION OF HUMAN PROCALCITONIN

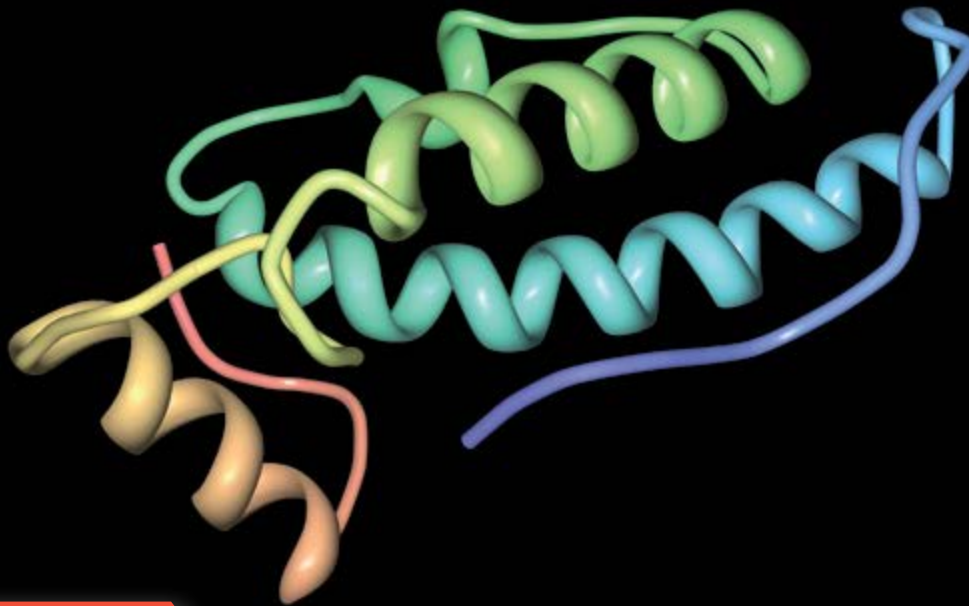
IVD CE

Human Procalcitonin ELISA

- › High sensitivity (15 pg/ml)
- › Excellent analytical characteristics
- › Validated for human serum and urine samples
- › Preliminary population and pilot study data

**SEPSIS
BACTERIAL INFECTION
INFLAMMATION
SEPTIC SHOCK**

HUMAN PROCALCITONIN ELISA



Introduction

Procalcitonin (PCT) the precursor of the hormone calcitonin is a 116 amino acid protein with a molecular mass of 13 kDa. It undergoes successive cleavages in the neuroendocrine cells of the thyroid to form three distinct molecules; calcitonin (32 amino acids); katalcalcin (21 amino acids) and N-terminal fragment called aminoprocaltitonin (57 amino acids). Procalcitonin belongs to a group of related proteins including calcitonin gene-related peptides I and II, amylin, adrenomodulin and calcitonin (CAPA peptide family).

Synthesis of procalcitonin is regulated by gene CALC-1. Under normal metabolic conditions procalcitonin is present in the C-cells of the thyroid gland. The level of procalcitonin in the blood of healthy individuals is low.

The risk of local bacterial infection occurs when the value of procalcitonin exceeds 0.25 ng/ml. The risk of systemic bacterial infection occurs when the value of procalcitonin exceeds 0.5 ng/ml. Bacterial lipopolysaccharide (LPS) has been shown to be a potent inducer of procalcitonin release into systemic circulation.

This release is not associated with an increase in calcitonin. Procalcitonin levels increase from 3 to 4 hours, peak at about 6 hours and then plateau for up to 24 hours. In contrast, C-reactive protein (CRP) levels rise between 12 and 18 hours after bacterial challenge. In blood serum, procalcitonin has a half-life of between 25 and 30 hours. A study showed that hepatocytes produce large amounts of procalcitonin following stimulation with TNF- α and IL-6. In acute pancreatitis,

procalcitonin closely correlates with the development of pancreatic infections. Since procalcitonin has been reported to be increased in different non-septic conditions such as major trauma, acute respiratory distress syndrome, rejection after transplantation, cardiogenic shock, severe burns and heat-stroke, the discriminative power of procalcitonin could be hampered in these particular patient categories. A recent study concluded that children with bacterial pneumonia had significantly higher procalcitonin levels than those with a viral aetiology, but there was a significant degree of overlap.

Procalcitonin has the greatest sensitivity and specificity for differentiating patients with Systemic Inflammatory Response Syndrome (SIRS) from those with sepsis, when compared to IL-2, IL-6, IL-8, CRP and TNF- α . Today procalcitonin is considered to be one of the earliest and most specific markers of sepsis.

The antibodies used in this ELISA are specific for human Procalcitonin. Several quantitative procalcitonin assays are available, including a rapid, semiquantitative procalcitonin test. No assay detects the 116 kDa procalcitonin peptide exclusively. All assays detect various portions of several calcitonin precursors, using a combination of antibodies. Following the above, we can mention our procalcitonin crossreactivity.

QUANTITATIVE DETERMINATION OF HUMAN PROCALCITONIN

BioVendor Human Procalcitonin ELISA (RD191006200R)

Intended use

The RD191006200R Human Procalcitonin ELISA is a sandwich enzyme immunoassay for the quantitative measurement of human procalcitonin.

- The total assay time is less than 2.5 hours
- The kit measures Procalcitonin protein in human serum and urine
- The kit measures Procalcitonin protein in serum of several mammalian species such as dog and sheep
- Assay format is 96 wells
- Quality Control is human serum based. No animal sera are used
- Standard is recombinant protein based
- Components of the kit are provided ready to use, concentrated or lyophilized

Clinical application

- Sepsis
- Bacterial infection
- Septic shock
- Inflammation

Test principle

In the BioVendor Human Procalcitonin ELISA, standards, quality controls and samples are incubated in microplate wells pre-coated with polyclonal anti-human procalcitonin antibody. After 60 minutes incubation and washing, HRP labelled polyclonal anti-human procalcitonin antibody is added and incubated with captured procalcitonin for 60 minutes. After another washing step, the remaining conjugate is allowed to react with the substrate solution (TMB). The reaction is stopped by addition of acidic solution and absorbance of the resulting yellow product is measured. The absorbance is proportional to the concentration of procalcitonin. A standard curve is constructed by plotting absorbance values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.

HUMAN PROCALCITONIN ELISA

CAT. NO.: RD191006200R

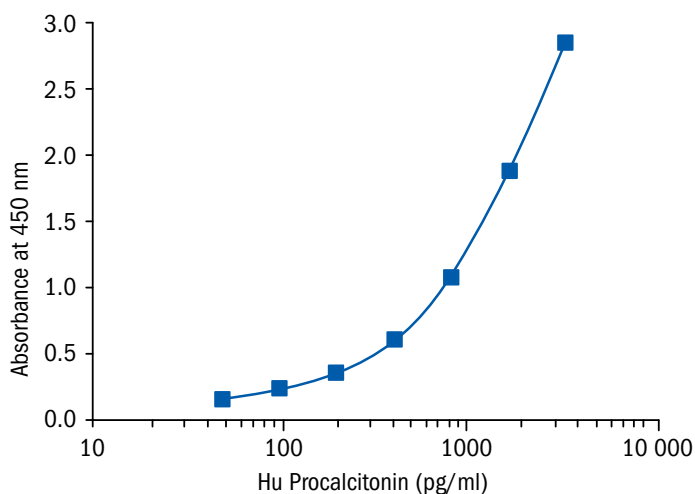
Assay format Sandwich ELISA, HRP-labelled antibody, 96 wells/kit

Samples Serum, Urine

Controls QC-High, QC-Low

Standards 50 to 3200 pg/ml

Limit of detection 15 pg/ml



HUMAN PROCALCITONIN ELISA

Precision

Intra-assay (Within-Run) (n=8)

Sample	Mean (pg/ml)	SD (pg/ml)	CV (%)
1	3 302.6	101.8	3.1
2	2 168.9	48.2	2.2

Inter-assay (Run-to-Run) (n=6)

Sample	Mean (pg/ml)	SD (pg/ml)	CV (%)
1	1 523.9	96.8	6.4
2	2 325.6	73.0	3.1

Spiking recovery

Serum samples were spiked with different amounts of human Procalcitonin and assayed.

Sample	Observed (pg/ml)	Expected (pg/ml)	Recovery O/E (%)
1	752.5	-	-
	3 281.9	3 152.5	104.1
	2 011.9	1 952.5	103.0
	1 375.3	1 352.5	101.7
2	2 217.3	-	-
	7 349.1	7 017.3	104.7
	4 563.1	4 617.3	98.8
	3 371.1	3 417.3	98.6

Linearity

Serum samples were serially diluted with Dilution Buffer and assayed.

Sample	Dilution	Observed (pg/ml)	Expected (pg/ml)	Recovery O/E (%)
1	-	3 465.7	-	-
	2x	1 639.5	1 732.9	94.6
	4x	846.9	866.4	97.7
	8x	430.2	433.2	99.3
2	-	2 558.9	-	-
	2x	1 225.3	1 279.5	95.8
	4x	641.8	639.6	100.3
	8x	332.5	319.8	103.9

Summary of protocol

- Reconstitute Master Standard , QC and prepare set of Standards
- Dilute serum samples (3x) and urine samples (2x)
- Add 100 µl Standards, QC and samples
- Incubate at RT for 1 hour/300rpm
- Wash plate 3 times
- Add 100 µl Conjugate solution
- Incubate at RT for 1 hour/300 rpm
- Wash plate 3 times
- Add 100 µl Substrate Solution
- Incubate at RT for 10 min
- Add 100 µl stop solution
- Read absorbance and calculate results

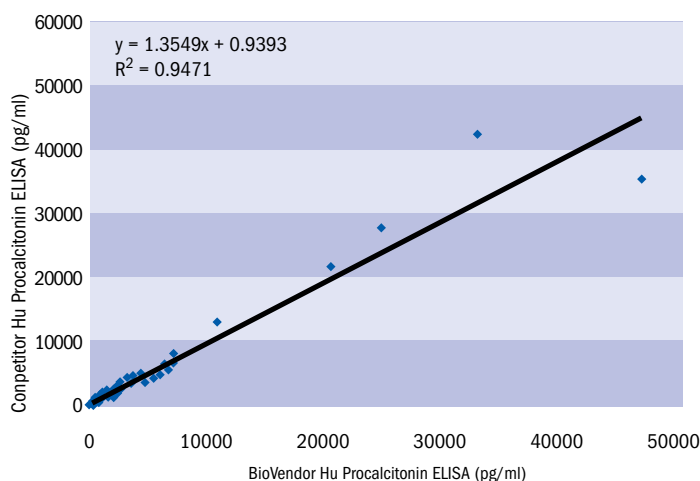
QUANTITATIVE DETERMINATION OF HUMAN PROCALCITONIN

Cross-reactivity

Mammalian serum Sample	Bovine	Cat	Dog	Goat	Hamster	Horse	Monkey	Mouse	Pig	Rabbit	Rat	Sheep
Observed cross-reactivity	no	no	yes	no	no	no	no	no	no	no	no	yes

Method Comparison

The BioVendor Human Procalcitonin ELISA was compared to another commercial ECLIA immunoassay, by measuring 67 serum samples. The following correlation graph was obtained.



Related products

- RD172006100 Procalcitonin Human *E. coli*
- RD194034200R Clusterin Human ELISA
- RD491034200R Clusterin Canine ELISA
- RD391034200CS Clusterin Rat ELISA
- RAP001 CRP Human ELISA
- RAP002 hsCRP Human ELISA
- RH931CRP01DCR hsCRP Canine ELISA
- RH971CRP01MR hsCRP Mouse ELISA
- RH951CRP01R hsCRP Rat ELISA
- RD194349200R MxA Protein Human ELISA
- RD191158100R Trefoil Factor 1 Human ELISA
- RD191159100R Trefoil Factor 2 Human ELISA
- RD191160200R Trefoil Factor 3 Human ELISA

References

1. Lee JY, Hwang SJ, Shim JW, Jung HL, Park MS, Woo HY and Shim JY: Clinical Significance of Serum Procalcitonin on Patients with Community-acquired Lobar Pneumonia. *Korean J Lab Med.* 2010, 30(4): 406-13
2. Pourakbari B, Mamishi S, Zafari J, Khairkhan H, Ashtiani MH, Abedini M, Afsharpaiman S and Rad SS: Evaluation of procalcitonin and neopterin level in serum of patients with acute bacterial infection. *Braz J Infect Dis.* 2010, 14(3): 252-255
3. Kang YA, Kwon SY, Yoon HI, Lee JH and Lee CHT: Role of C-Reactive Protein and Procalcitonin in Differentiation of Tuberculosis from Bacterial Community Acquired Pneumonia. *The Korean Journal of Internal Medicine.* 2009, 24(4) 337-342
4. Nanda N and Juthani-Mehta M: Novel Biomarkers for the Diagnosis of Urinary Tract Infection – A systematic Review. *Biomarker Insights.* 2009, 4: 111-121
5. Sand M, Trullen XV, Bechara FG, Pala XF, Sand D, Landgrafe G and Mann B: A Prospective Bicenter Study Investigating the Diagnostic Value of Procalcitonin in Patients with Acute Appendicitis. 2009, 43: 291-297
6. Summah H and Qu JM: Biomarkers: A definite Plus in Pneumonia. *Mediators of Inflammation.* 2009, ID 675753, 1-9
7. Schultz MJ and Determann RM: PCT and sTREM-1: The markers of infection in critically ill patients? *Med Sci Monit.* 2008, 14(12): 241-247
8. Arkader R, Troster EJ, Lopes MR, Júnior RR, Carcillo JA, Leone C and Okay TS: Procalcitonin does discriminate between sepsis and systemic inflammatory response syndrome. *Arch Dis Child.* 2006, 91: 117-120
9. Pecile P, Miorin E, Romanello C, Falletti E, Valent F, Giacomuzzi F and Tenore A: Procalcitonin : A Marker of Severity of Acute Pyelonephritis Among Children. *Pediatrics.* 2004, 114(2): 249-254
10. Carrol ED, Thomson APJ and Hart CA: Procalcitonin as a marker of sepsis. *International Journal of Antimicrobial Agents.* 2002, 20: 1-9
11. Smolkin V, Koren A, Raz R, Colodner R, Sakran W and Halevy R: Procalcitonin as a marker of acute pyelonephritis in infants and children. *Pediatr Nephrol.* 2002, 17: 409-412
12. Harbarth S, Holeckova K, Froidevaux C, Pittet D, Ricou B, Grau GE, Vadas L, Pugin J and the Geneva Sepsis Network: Diagnostic Value of Procalcitonin, Interleukin -6 and Interleukin -8 in Critically ill Patients Admitted with Suspected Sepsis. *Am J Respir Crit Care Med.* 2001, 164: 396-402
13. Maruna P, Nedělníková and Gürlich R: Physiology and Genetics of Procalcitonin. *Physiol. Res.* 2000, 49: 57-61

Contact Information



BioVendor – Laboratorní medicína a.s.

Karasek 1767/1, 621 00 Brno, Czech Republic
Phone: +420 549 124 185, Fax: +420 549 211 460
E-mail: info@biovendor.com

BioVendor GmbH

Otto-Hahn-Straße 16, 34123 Kassel, Germany
Phone: +49 6221 4339 100, Fax: +49 6221 4339 111
E-mail: infoEU@biovendor.com

➤ www.biovendor.com

BioVendor GesmbH

Gaudenzdorfer Gürtel 43-45, 1120 Vienna, Austria
Phone: +43 1 890 9025, Fax: +43 1 890 5163
E-mail: infoAustria@biovendor.com

BioVendor, LLC

128 Bingham Rd., Suite 1300, Asheville, NC 28806, USA
Phone: +1-800-404-7807, Phone: +1-828-575-9250
Fax: +1-828-575-9251, E-mail: infoUSA@biovendor.com