

Procalcitonin FS

**The reliable alternative,
when time matters**



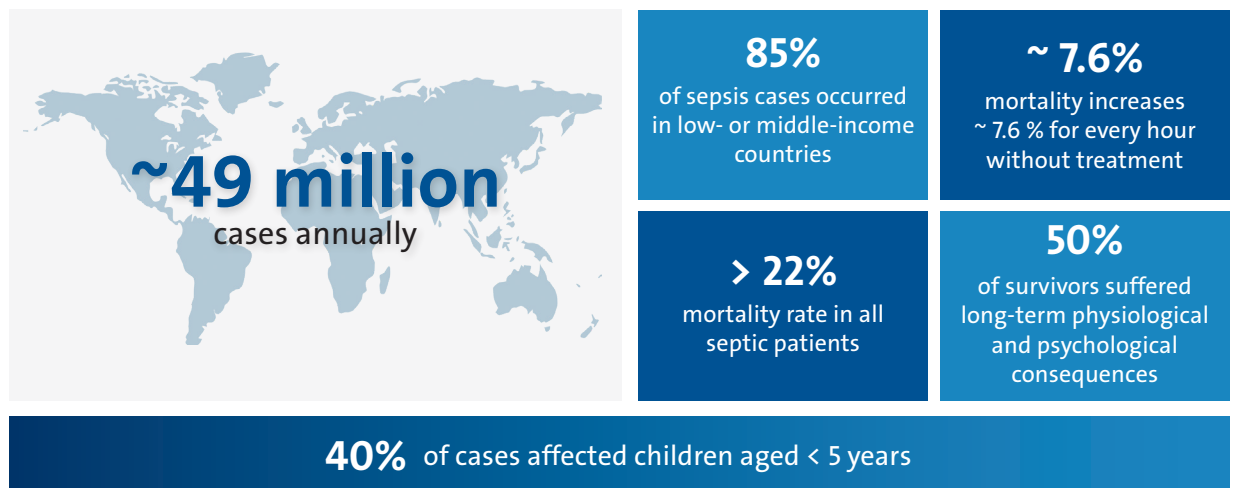
Precise | Cost-efficient | Time-saving
DiaSys. Total confidence in patient results.

DiaSys

Diagnostic Systems

CHOOSING QUALITY.

Sepsis - a leading cause of death in hospitals [1-6]



What is Procalcitonin? [7-13]

Procalcitonin (PCT), the precursor of the hormone calcitonin, is a 116 amino acid protein with a molecular weight of 13 kDa. In healthy individuals PCT is primarily expressed in thyroid C cells and is enzymatically cleaved to calcitonin, a calcium-regulating peptide. Upon stimulation by bacterial toxins and inflammatory cytokines PCT is expressed in the tissue of all organs. Thus, in patients with systemic bacterial infections, the PCT concentrations may rise from < 0.1 ng/mL up to 1000 ng/mL within a few hours, therefore PCT measurement is also recommended by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) for patients with COVID-19.

Benefits of PCT [2, 13-15]

In comparison to other sepsis biomarkers, PCT shows several advantages:

- Fast in sepsis diagnosis and monitoring
- Good specificity and sensitivity for sepsis
- Beneficial kinetic in comparison to other parameters:
Early onset (3 - 6h) and short half-life (~ 12 - 24h)
- Sensitive to bacterial origin

However, PCT is no stand-alone parameter. In order to interpret results, they should always be placed into clinical context (temperature, blood pressure, heart rate, respiratory rate).

Procalcitonin FS

Procalcitonin FS is a reagent for quantitative in vitro determination of PCT in human serum or heparin plasma on automated photometric systems.

The assay offers a reliable alternative, when time matters in sepsis management.

Assay features and advantages

Procalcitonin FS is applicable on DiaSys respons[®]920, respons[®]940 and BioMajesty[®] JCA-BM6010/C, as well as many other common clinical chemistry analyzers. Therefore, the assay is suitable for routine measurement of PCT in any clinical laboratory.

Fluid-stable,
2-component reagent

Particle enhanced
immunoturbidimetric
method

Performance
comparable to
competitor assays

Suitable for routine
measurement of PCT in
sepsis management

Applicable on
photometric
systems

Cost-efficient and
reliable

Assay performance

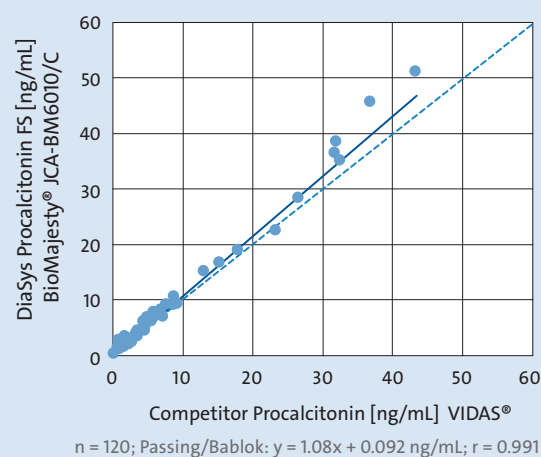
- Measuring range from 0.27 – 50 ng/mL (LoD depending on the analyzer)
- Minimized interference by standard blood components, various antibiotics and other drugs commonly used in sepsis and ICU patients
- Good precision at clinical cut-offs
- 5 weeks onboard stability, 2 weeks calibration stability on BioMajesty[®] JCA-BM6010/C
- Method comparison shows concordance with competitor method at all clinical cut-offs
- Good performance scientifically proven by Dupuy AM, et al. in Diagnostics, 2020

Precision

In series*	Mean [ng/mL]	CV [%]
Sample 1	0.602	5.11
Sample 2	1.96	2.96
Sample 3	9.43	2.49
Total precision*	Mean [ng/mL]	CV [%]
Sample 1	0.566	5.94
Sample 2	2.23	2.90
Sample 3	10.8	2.04

*on BioMajesty[®] JCA-BM6010/C

Method comparison



Leading technology in fluid-stable reagents from DiaSys

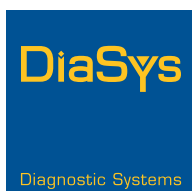
- More than 30 years experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

DiaSys offers reagent kits with dedicated calibrators and controls for automated use. Detailed information about Procalcitonin FS is available on our microsite www.procalcitonin.de and in the product catalog.

References

- ¹ Rudd KE, et al., The Lancet, 2020, 395, 200–211
- ² Schuetz P, et al. BMC Med, 2011, 9, 107.
- ³ Kip MMA, et al. J Med Econ, 2015, 18, 944–953.
- ⁴ Fleischmann C, et al. Am J Respir Crit Care Med, 2016, 193, 259–272
- ⁵ Kumar A, et al. Critical care medicine 2006, 34, 6 1589-1596.
- ⁶ <https://www.worldsepsisday.org/> World Sepsis Fact Sheet last updated May 2020.
- ⁷ Maruna P. et al. Physiol Res. 2000; 49(Suppl 1): S57–S61.
- ⁸ Müller B. et al. J Clin Endocrinol Metab. 2001; 86(1): 396-404.
- ⁹ Becker K.L. et al. The Journal of Clinical Endocrinology & Metabolism. 2004; 89(4): 1512-1525.
- ¹⁰ Becker K.L. et al. British journal of pharmacology. 2010; 159(2): 253-264.
- ¹¹ Harbarth S. et al. Am J Respir Crit Care Med. 2001; 164: 396–402.
- ¹² IFCC Information Guide on COVID-19 <https://www.ifcc.org/resources-downloads/ifcc-information-guide-on-covid-19-introduction/> [last accessed: October 22nd 2021]
- ¹³ Meisner M. Procalcitonin – Biochemie und klinische Diagnostik. 1. Auflage Bremen: UNI-MED-Verlag 2010.
- ¹⁴ Christ-Crain M, Swiss Med Wkly, 2005, 135, 451–460
- ¹⁵ Nelson GE, et al. BioMed Research International, 2014, 2014, 1–11.

Handed over by:



DiaSys
Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

Phone: +49 6432 9146-0
Fax: +49 6432 9146-32
E-Mail: info@diasys.de
www.diasys-diagnostics.com



820139 | 2022-10