Procalcitonin (PCT)

Early detection of systemic bacterial infections

B·R·A·H·M·S PCT-Q – the fast and reliable Procalcitonin (PCT) test

thermo scientific

It’s all about time

Use of a rapid PCT test allows early detection of systemic bacterial infections

Severe bacterial infection can rapidly progress to sepsis* and septic shock if not treated appropriately within a short time. Therefore it is important to detect this infection as early as possible to avoid further progression of the disease.

Since laboratory service is not always available around the clock, rapid testing is an alternative way of acquiring information at any time. The rapid test **Thermo Scientific™ B·R·A·H·M·S PCT™-Q** meets this clinical demand for immediate confirmation or exclusion of a severe bacterial infection or sepsis.

B·R·A·H·M·S PCT-Q delivers information for acute diagnostic and therapeutic decision-making within 30 minutes.

B·R·A·H·M·S PCT meets the needs of sepsis diagnosis

Among the currently available biomarkers PCT is considered the most reliable and specific diagnostic parameter for severe systemic bacterial infections due to its rapid induction and high sensitivity and specificity.[2–7]

Early response
Levels increase within 3–6 hours after bacterial challenge[8]

Highly sensitive and specific
A mean sensitivity of 0.77 and a mean specificity of 0.79 to discriminate sepsis from SIRS of non-infectious origin – based on meta-analysis of 3244 patients[9]

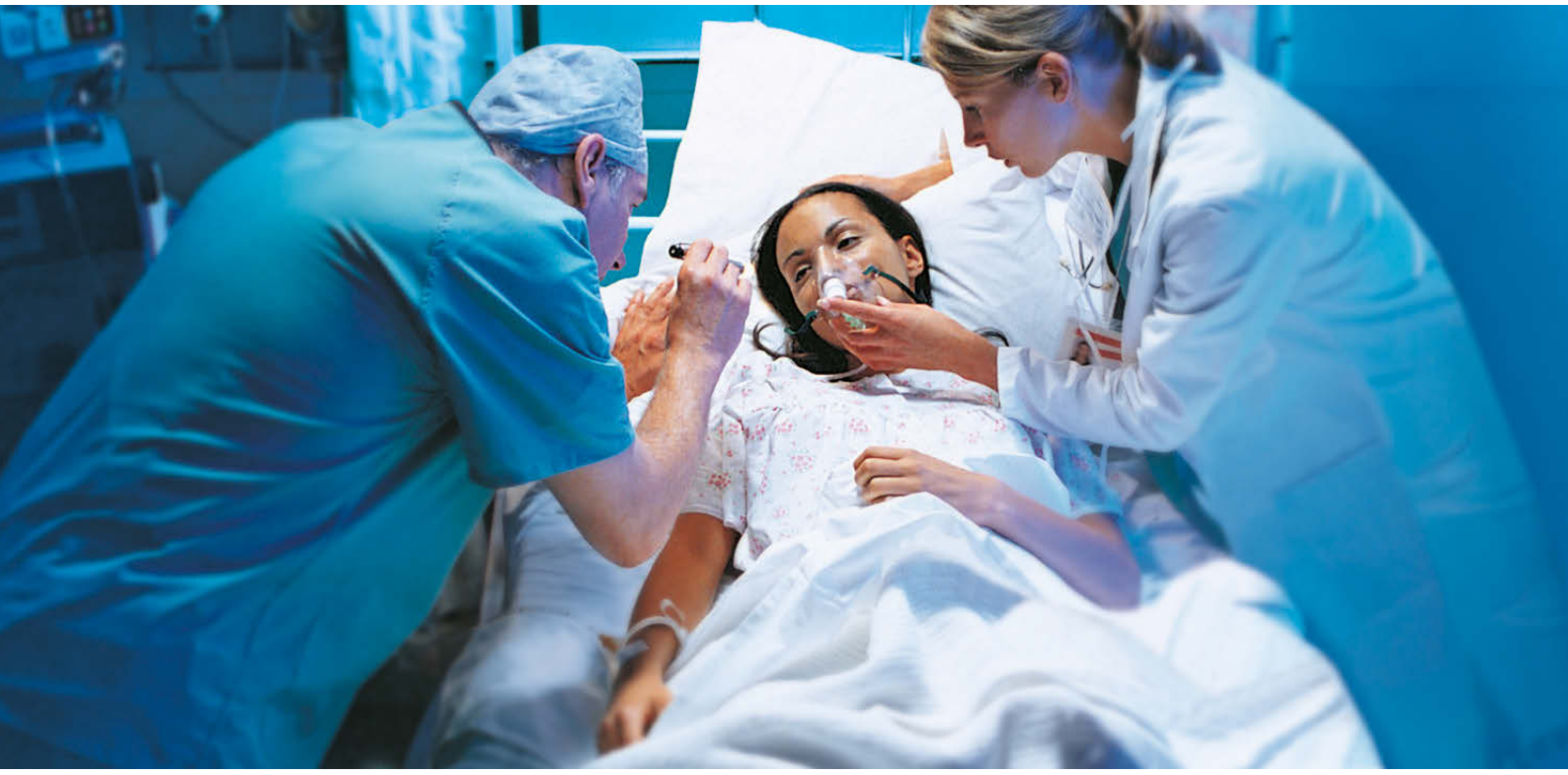
* According to Sepsis-3 definition[1]

Clinical utility of B·R·A·H·M·S PCT-Q

Early detection
of systemic bacterial infection (sepsis)

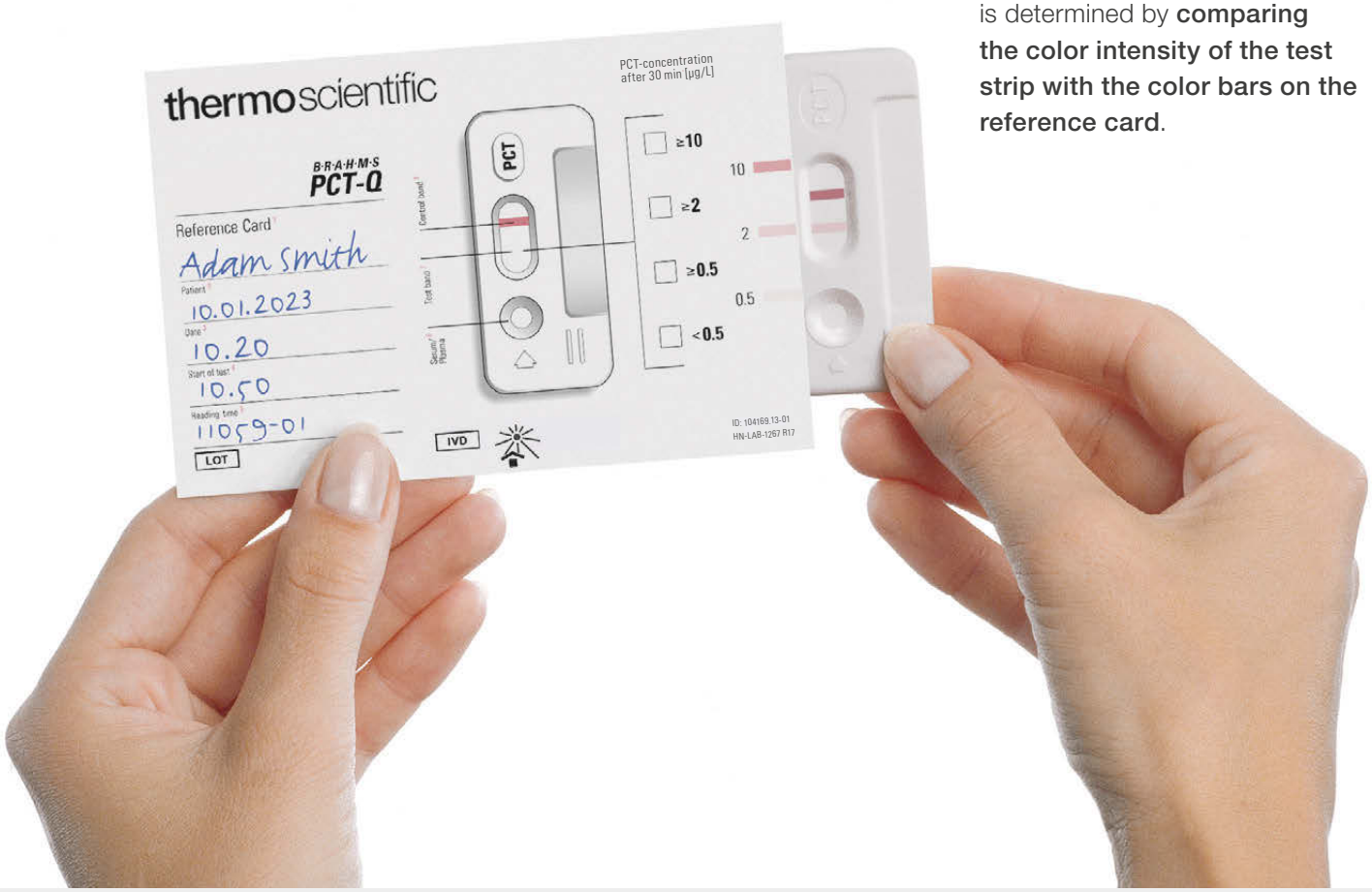
Differential diagnosis
of systemic bacterial infection vs. inflammatory reaction due to other causes (i.e. non-infection-related inflammatory reactions, viral infections, localized bacterial infections etc.)

Monitoring of patients at risk
for nosocomial infection (i.e. patients after surgical intervention, patients following organ transplant, patients under immunosuppression, patients with other risk factors)

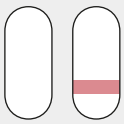


Easy to use at any time in any hospital

Simple to read test results

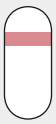


The PCT concentration range is determined by **comparing the color intensity of the test strip with the color bars on the reference card**.



Not valid

No band or only test band visible: Tests which show no control band are **not valid** and may not be evaluated.



Negatively valid

Only control band visible: Tests which show only a control band are **negatively valid**. The PCT concentration is <0.5 µg/L.

Positively valid

Control and test band visible: Tests which show both a control band and a test band are **positively valid**.

Result is valid only in case of a clearly visible **control band**.

High reliability and reproducibility

B·R·A·H·M·S PCT-Q shows a high degree of reliability and reproducibility in the determination of serum/plasma PCT concentrations. Semi-quantitative concentration ranges obtained with B·R·A·H·M·S PCT-Q **correlate closely** with quantitative results of automated B·R·A·H·M·S PCT KRYPTOR™. A comparison of B·R·A·H·M·S PCT-Q with B·R·A·H·M·S PCT sensitive KRYPTOR using 143 human serum samples gave an agreement of >90%.[10]

PCT cut-off	0.5 µg/L PCT	2.0 µg/L PCT
Concordance	94%	97%
Sensitivity	96%	97%
Specificity	92%	97%

Table 1. Performance of B·R·A·H·M·S PCT-Q compared with reference assay (B·R·A·H·M·S PCT sensitive KRYPTOR) results.

Sample type
Serum or plasma

Sample volume
200 µL (see instructions for use)

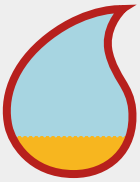
Temperature
Performed at room temperature

Reliable detection of systemic bacterial infections

The semi-quantitative measurement range of B·R·A·H·M·S PCT-Q is correlated to **three reference concentrations (0.5 µg/L, 2 µg/L, 10 µg/L)** which are of significance in the differential diagnosis of clinically relevant bacterial infection and sepsis).

This calibration makes it possible to detect severe bacterial infection (limit 0.5 µg/L) and assess the risk of progression to sepsis and septic shock.[1] Thus allowing early decision on the appropriate therapeutic measures.

PCT levels rise with increasing severity of infection[3,10]



<0.5 µg/L

Systemic infection unlikely

≥0.5 – <2 µg/L

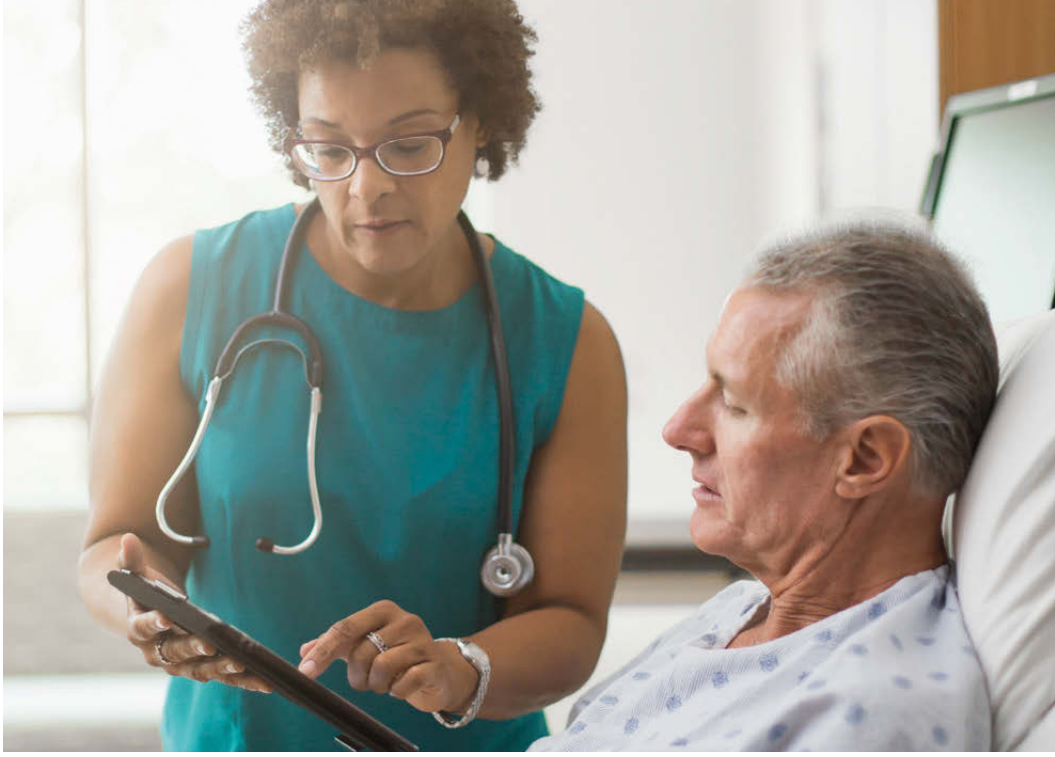
Systemic infection is possible. Moderate risk for progression to sepsis with organ dysfunction.

≥2 µg/L

Systemic infection (sepsis) is likely, unless other causes are known. A high risk for progression to sepsis or septic shock exists.

Figure 1. PCT reference ranges and their correlation with the patient's clinical condition[3,10]

Note: As an expression of individually different immune responses and different clinical situations, the same focus of infection may be associated with varying individual elevations in PCT concentrations. According to the clinical situation, the cut-offs may vary. The reference ranges above are therefore given for orientational purpose only.
Therefore, clinicians should use the PCT results in conjunction with other laboratory findings and the patient's clinical signs, and interpret the concrete values in the context of the patient's clinical situation.
Age-specific PCT values exist for neonates to rule out maternal-fetal bacterial infection, in the first 72 hours of life.[10]



PCT levels should always be interpreted in the clinical context

Increased PCT levels may not always be related to infection.

Situations where PCT can be elevated by non-infectious causes

- Major trauma and/or recent surgical procedure including extracorporeal circulation or burns
- Treatment with OKT3 antibodies, OK-432, interleukins, TNF-alpha and other drugs stimulating the release of pro-inflammatory cytokines or resulting in anaphylaxis
- Active medullary C-cell carcinoma, small cell lung carcinoma, or bronchial carcinoid
- Acute or chronic viral hepatitis and/or decompensated severe liver cirrhosis (Child-Pugh Class C) and/or acute liver failure
- Prolonged or severe cardiogenic shock, prolonged severe organ perfusion anomalies or after resuscitation from cardiac arrest
- Biliary pancreatitis, chemical pneumonitis or heat stroke
- Kawasaki, Still's Disease or Bell's Palsy
- Invasive fungal infections (e.g. *candidiasis, aspergillosis*) or acute attacks of *plasmodium falciparum malaria*
- Infection with certain atypical pathogens, such as *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae*
- Peritoneal dialysis or hemodialysis treatment
- Also severity of renal failure or insufficiency, may influence PCT values and should be considered as potentially confounding clinical factors when interpreting PCT values
- Mushroom poisoning
- Preeclampsia
- Paracetamol intoxication

Low PCT levels do not automatically exclude the presence of bacterial infection.[4] Such low levels may be obtained, *e.g.*, during the early course of infections, in localized infections and in subacute endocarditis. Therefore, follow-up and re-evaluation of PCT in clinical suspicion of infection is pivotal.

Values found below the detection limit of B·R·A·H·M·S PCT-Q

In case of B·R·A·H·M·S PCT-Q, a test result below 0.5 µg/L should not automatically interpreted as an absence of bacterial infection as the test sensitivity does not allow a differentiation of uninfected (values below 0.1 µg/L) and local infection (values usually below 0.5 µg/L).[4] Therefore, in case of a B·R·A·H·M·S PCT-Q result <0.5 µg/L in the presence of clinical signs of infection it is recommended to re-check the PCT value by use of a sensitive quantitative PCT assay.

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"In sepsis, time is critical.
Fast PCT results support me in early and safe clinical decision making."

References

1. Rhodes et al., Intensive Care Med 2017; 43 (3): 304-77
2. Chiesa et al., Clin Infect Dis 1998; 26: 664-72
3. Harbarth et al., Am J Resp Crit Care Med 2001; 164: 396-402
4. Meisner M. Procalcitonin – Biochemistry and Clinical Diagnosis, ISBN 978-3-8374-1241-3, UNI-MED, Bremen 2010
5. Müller et al., Crit Care Med 2000; 28(4): 977-83
6. Simon et al., Clin Infect Dis 2004; 39(2): 206-17
7. Van Rossum et al., Lancet Infect Dis 2004; 4(10): 620-30
8. Brunkhorst et al., Int Care Med 1998; 24: 888-92
9. Wacker et al., Lancet Infect Dis 2013; 13: 426-35
10. B·R·A·H·M·S PCT-Q Instruction for Use, V3

Clinical Diagnostics

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