B-R-A-H-M-S PCT direct

Whole blood Procalcitonin test at point of care

Tailored for emergency use

Faster diagnosis can save lives

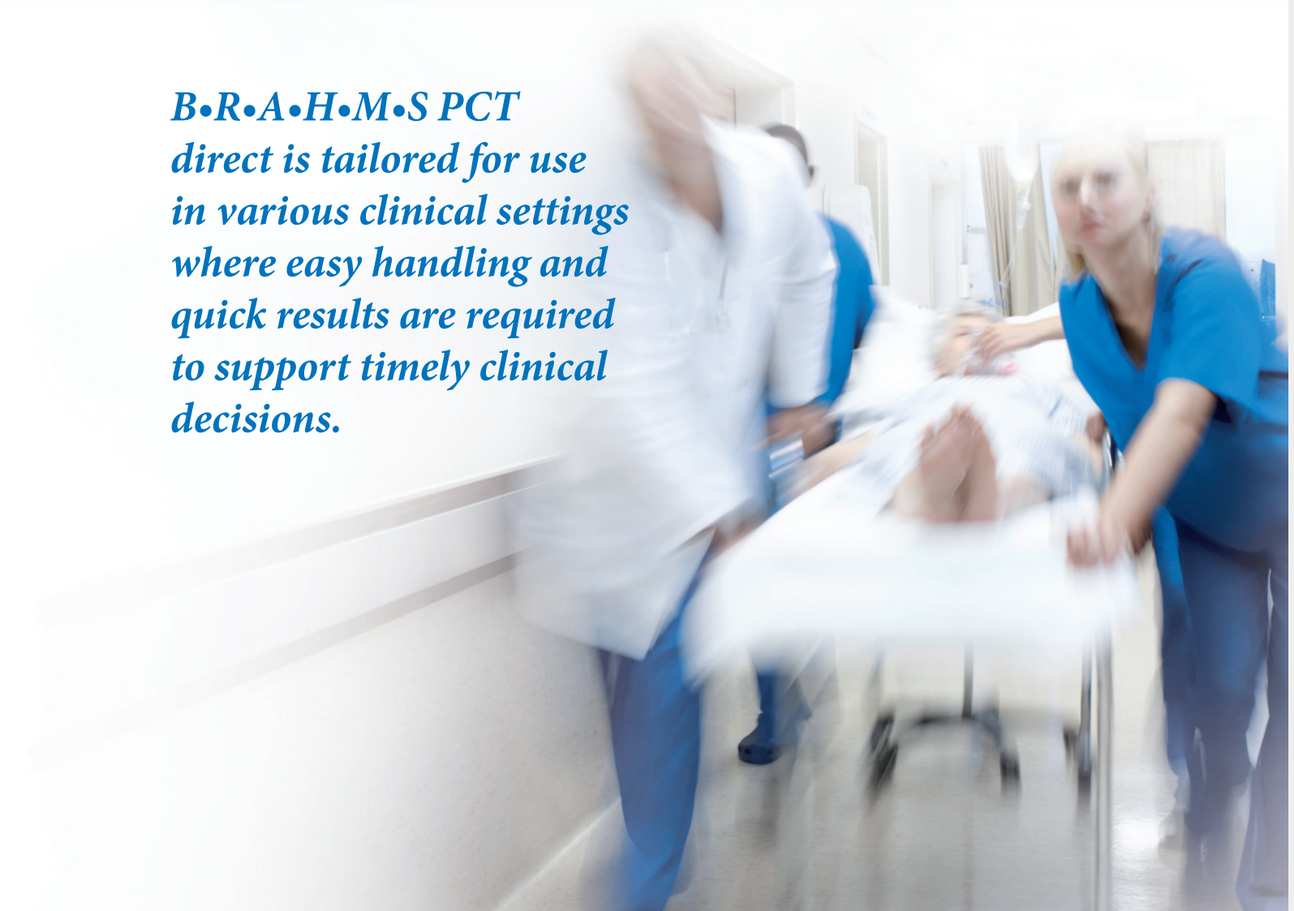
Need for rapid infection diagnosis and clinical decisions in acute care settings

Clinically relevant bacterial infections can rapidly progress to severe sepsis and septic shock if not treated appropriately within a short time.[1]

Therefore it is important to detect infections as early as possible. Procalcitonin (PCT) is considered a reliable and specific biomarker to aid in the diagnosis of clinically relevant bacterial infections early.[2,3]

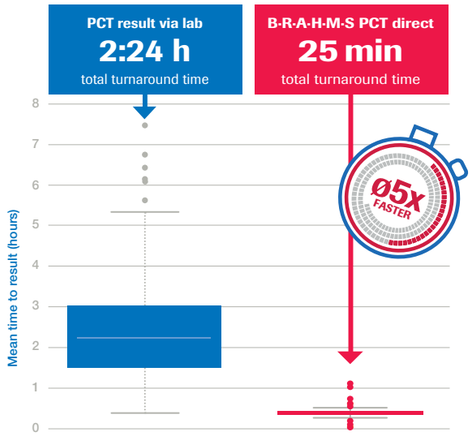
B·R·A·H·M·S PCT direct provides reliable PCT test results at the point of care, 24/7, and can aid in:

- confirming or challenging the initial suspicion of bacterial infection, allowing the identification of patients that benefit from antibiotic treatment[4]
- assessing the severity and the prognosis of the outcome of bacterial infection or sepsis[4], enabling quick and appropriate patient management[5,6]



B•R•A•H•M•S PCT direct is tailored for use in various clinical settings where easy handling and quick results are required to support timely clinical decisions.

Immediate and reliable decision making



B·R·A·H·M·S PCT direct shows a significantly reduced total turnaround time (Figure 1) providing a rapidly available, reliable result for immediate decision making at point of care.

Figure 1 Using the B·R·A·H·M·S PCT direct test reduced the median time to result to less than half an hour independent of daytime or lab service/ logistics (total turnaround time of lab test with a mean of 2:24 h, ranging from 30 min to 7:28 h) (n=303)[6]

Just one drop of blood needed

B·R·A·H·M·S PCT direct requires only a low blood volume (20 µL) from either venous or capillary finger-prick blood making it ideal for patients where sample volume may be an issue.

With the B·R·A·H·M·S PCT direct whole blood test the information on the patient's PCT level is available at point of care rapidly from just one drop of blood.

B·R·A·H·M·S direct Reader

Designed for point of care use

Easy data handling

Input

- Supervisor and operator settings
- Data entry via barcode scanner or manually
- Pre-installed menu languages: English, French, German, Italian, Spanish, Japanese; further languages can be uploaded

Output

- Thermal printer integrated
- Laboratory information system (LIS) connectivity with middleware

Securing quality

- B·R·A·H·M·S direct Reader Control & Liquid QC
- QC lock functionality

High data storage capacity

- 2,000 operators/supervisors
- 30 test lots by expiry dates
- 15 liquid QC lots by expiry dates
- 15 Reader Control lots by expiry dates
- 200 patient results
- 50 liquid QC results

Quick, easy, and precise

20 µL of capillary or venous whole blood sample

Incubation and measurement in B·R·A·H·M·S direct Reader

Quantitative test result available in 20 minutes

Results printed and transferred via middleware to LIS

Reliable in clinical use

High clinical concordance of B·R·A·H·M·S PCT direct with laboratory test

	Cut-off [µg/L]	Sensitivity	Specificity	Concordance of result to reference method
Venous blood	0.25	92.4%	93.1%	**93%**
	0.5	91.8%	94.6%	**93%**
Capillary blood	0.25	88.7%	94.2%	**91%**
	0.5	92.0%	96.7%	**95%**

Table 1 Performance comparison B·R·A·H·M·S PCT direct to B·R·A·H·M·S PCT reference method (EDTA blood, n=338; capillary blood, n=140)[7]

Close correlation with automatized B·R·A·H·M·S PCT reference assays

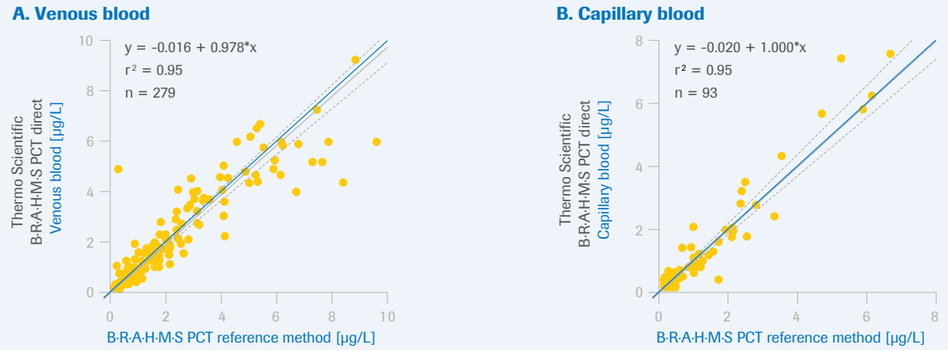


Figure 2 Correlation of results using B·R·A·H·M·S PCT direct obtained with capillary blood or venous blood (Figure A and B, respectively) compared to B·R·A·H·M·S PCT reference method[7]

Indications for PCT determination using B·R·A·H·M·S PCT direct

Aid in early diagnosis of bacterial infection and sepsis

- 20 µL whole blood (venous or capillary)
- Assay sensitivity: LoQ (limit of quantification) of 0.22 µg/L
- Immediate identification of patients with elevated PCT and increased risk for severe bacterial infection

Rapid decision whether to start antibiotic treatment

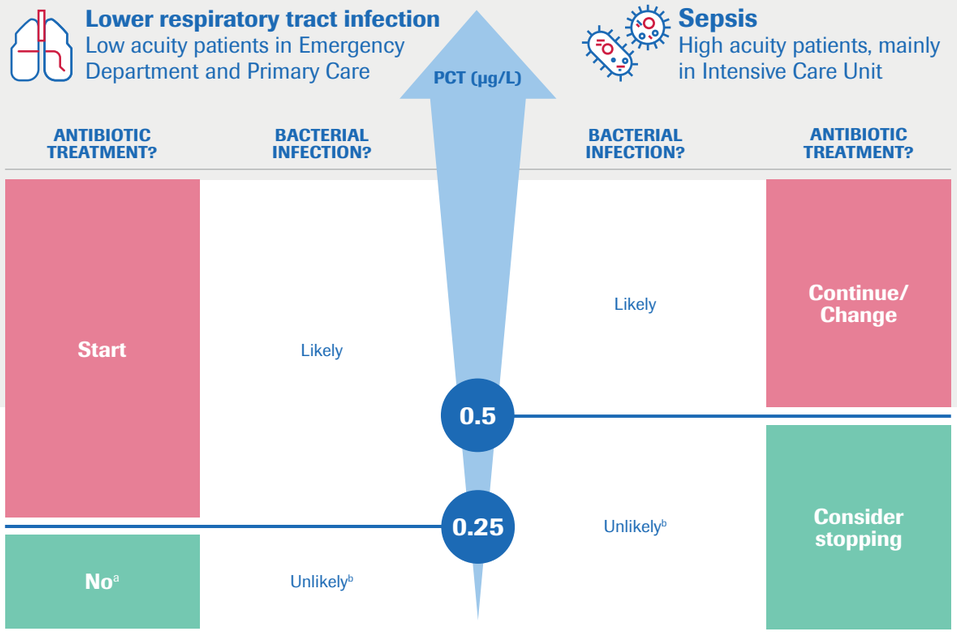
- Low-risk patients: antibiotics may be withheld if the PCT values are below the cut-off 0.25 µg/L
- High-risk patients: negative test should not prevent treatment

Monitoring and assessment of successful antibiotic therapy

Early identification of treatment failure within the measuring range of 0.22 µg/L to 10 µg/L

Interpretation of PCT results

B·R·A·H·M·S PCT direct in conjunction with clinical assessment of the patient and other laboratory parameters enables an **early diagnosis of clinically relevant bacterial infection and sepsis** and helps to **decide on antibiotic therapy** for patients with sepsis or lower respiratory tract infection.



Cut-off levels of clinical algorithms according to patients' acuity adapted from Schuetz, P. et al. (2011)[8]

a. Consider use of antibiotics if patients are clinically unstable, have strong evidence of pneumonia, are at high risk, or need hospitalization
b. Low risk of significant bacterial infection or sepsis; consider other diagnoses

Note: The PCT results should always be evaluated in the context of the total clinical evaluation of the patient.

B·R·A·H·M·S PCT direct – *For immediate decisions 24/7*

Sensitivity: LoQ of 0.22 µg/L allows diagnostic assessment and clinical decision making in the emergency room or other near patient settings

Only 20 µL whole blood from a finger prick or from venous puncture: Ideal for patients where sample volume may be an issue

Short total turnaround time: 25 minutes – available in any clinical department 24 hours a day, 7 days a week

Optimal fit to data management: Data input by scanner and reader connectivity to the laboratory information system (LIS)

Independent from laboratory service: Ideal for places that do not have easy/ full-time access to lab, off-site locations etc.

Ø5X FASTER

B·R·A·H·M·S PCT direct is tailored for emergency use and gives fast results at any time at point of care

Accelerate treatment decisions with B·R·A·H·M·S PCT direct

References

1. Kumar, A. et al. (2006). *Crit Care Med*, 34(6), 1589–96
2. Harbarth, S. et al. (2001). *Am J Respir Crit Care Med*, 164, 396–402
3. Schuetz, P. et al. (2019). *Clin Chem Lab Med,* 57(9): 1308–1318
4. B·R·A·H·M·S PCT direct Instructions for Use_R8.1
5. Schuetz, P. et al. (2009). *JAMA*, 302(10), 1059–1066
6. Kutz, A. et al. (2016). *Clin Chem Lab Med*, 54(4), 577–84
7. Velly L. et al. (2019), *Critical Care*, 23 (Suppl 2):P028
8. Schuetz, P. et al. (2011). *Arch Intern Med*, 171(15), 1322–31

Not all products are FDA cleared. Availability of products is related to the registration status in the countries.

The manufacture and/or use of this product is covered by one or more of the following patents: patents/brahms.com

Published by
Roche Diagnostics International Ltd
Forrenstrasse 2
6343 Rotkreuz, Switzerland

© 2020 All trademarks mentioned enjoy legal protection.