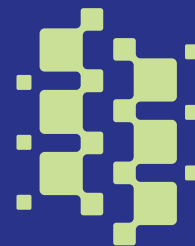


# Vitros<sup>®</sup> B·R·A·H·M·S Procalcitonin (PCT) Assay



## A high-quality assay to inform better treatment decisions

Sepsis is a life-threatening emergency. Infections can lead to sepsis when the infection triggers an uncontrolled response in the body and can rapidly lead to deteriorating health conditions and death, if not treated appropriately. The infection can start before a person goes into the hospital, however, healthcare-associated infections are one of the most frequent types of adverse events during hospital care worldwide.

Procalcitonin (PCT) is a superior biomarker for the diagnosis of serious bacterial infection and is used primarily to differentiate between bacterial and nonbacterial drivers of infection. PCT is used to monitor effective antibiotic treatment, including when antibiotics should be discontinued. This helps minimize the overuse of antibiotics, which is a main driver in antibiotic resistance. In fact, the World Health Organization (WHO) has listed procalcitonin as the only biomarker eligible to guide antibiotic therapy initiation or discontinuation of sepsis.

The Vitros B·R·A·H·M·S PCT assay combines the quality of B·R·A·H·M·S with the power of Vitros to enable clinicians make faster and better informed treatment plans from diagnosis through to resolution.

### Excellent analytical and operational performance

Measuring range: 0.030-100 ng/mL (0.030-100 µg/L)

LOD: 0.007 ng/mL (0.007 µg/L)

LOQ (claimed): 0.030 ng/mL (0.030 µg/L)

LOQ (observed at 20% CV): 0.013 ng/mL (0.013 µg/L)

Precision at clinical decision points (within lab):

- <3.9% at 0.100 ng/mL
- <3.5% at 0.250 ng/mL
- <3.7% at 0.500 ng/mL
- <4.0% at 2.00 ng/mL
- <4.1% at 10 ng/mL

Calibration interval: 56 days

Vitros system-to-system correlation: within <3.7%

Not impacted by biotin interference

### Vitros B·R·A·H·M·S PCT assay delivers:

#### Trust in results for laboratories:

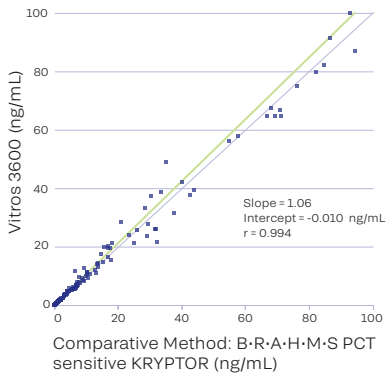
- High analytical sensitivity and specificity
- Accurate results through the quantification of endogenous interferences, hemolysis, icterus and turbidity
- Proven high quality with >6 Sigma metric
- Maximize efficiency with long calibration interval of 56 days
- Save time with 96.5% of results delivered to clinicians without the need for repeat tests
- Fast turnaround time of 24 minutes to first result
- Protect precious samples with small sample volume of 30 µL

#### Confidence in decisions for clinicians:

- Early diagnosis of severe bacterial infections and sepsis to help save lives
- Therapeutic guidance for starting and safely stopping antibiotic treatment
- Excellent analytical correlation and clinical concordance to B·R·A·H·M·S method at clinical decision points

# Vitros B·R·A·H·M·S Procalcitonin Assay

## Excellent analytical correlation



## Excellent clinical concordance

Clinical concordance to B·R·A·H·M·S method at clinical decision points

0.1 ng/mL	98.5%
0.25 ng/mL	98.0%
0.5 ng/mL	97.4%
2.00 ng/mL	97.8%
10 ng/mL	98.0%

Product code	Vitros Immunodiagnostic products item	Configuration
6905558	B·R·A·H·M·S PCT Reagent	100 tests
6905559	B·R·A·H·M·S PCT Calibrator Pack	2 levels, 1mL vials
6905560	B·R·A·H·M·S PCT Controls	3 levels, 1mL vials

## Intended use

For the quantitative measurement of procalcitonin (PCT) in human serum and plasma (lithium heparin and EDTA) using the Vitros ECI/ECiQ/3600 immunodiagnostic systems and the Vitros 5600/XT 7600 integrated systems.

The Vitros B·R·A·H·M·S PCT test is indicated as an aid to be used in conjunction with clinical evaluation for:

- The early detection and differential diagnosis of clinically relevant bacterial infections
- The assessment of the degree of severity and the prognosis of the outcome of systemic bacterial infection, sepsis, severe sepsis and septic shock
- Identifying patients that benefit from antibiotic treatment
- Monitoring of antibiotic therapy within the measuring range
- The assessment of successful antibiotic therapy in patients with suspected or confirmed bacterial infection

## References

1. Ortho Clinical Diagnostics (2020). Vitros Immunodiagnostic Products B·R·A·H·M·S PCT Reagent Pack and Calibrators Instructions For Use. IFU PCT GEM1370\_XUS\_EN. Raritan, NJ USA.
2. Foster M, Vealey J, Barba M. Best Practices in Laboratory Operations – Advances in Acquisition Decision Criteria. Business Briefing Report : Labtech 2004.
3. Harbarth S, Holeckova K, Froidevaux C et al. 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.
4. Müller B, Becker K, Schchinger H et al., Calcitonin precursors are reliable markers of sepsis in a medical intensive care unit. *Crit Care Med.* 2000; 28 (4): 977-83.
5. Brunkhorst FM, Wegscheider K, Forycki ZF, et al. Procalcitonin for early diagnosis and differentiation of SIRS, sepsis, severe sepsis, and septic shock. *Intensive Care Med.* 26:148-152; 2000.
6. Branche A, Neeser O, Müller B et al. Procalcitonin to guide antibiotic decision making. *Curr Opin Infect Dis.* 2019;32(2):130-135.
7. Schuetz P, Bolliger R, Merker M, et al. Procalcitonin-guided antibiotic therapy algorithms for different types of acute respiratory infections based on previous trials. *Expert Rev Anti Infect Ther.* 2018;16(7):555-564.
8. Simon L, Gauvin F, Amre D. et al. Serum Procalcitonin and C-Reactive protein levels as markers of bacterial infection: A Systematic Review and meta-analysis. *Clin Infect Dis.* 2004, 39(2): 206-217.

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