VITROS® B·R·A·H·M·S PCT

The Power of B·R·A·H·M·S with the Difference that only VITROS can Deliver

Sepsis

- Life-threatening clinical condition caused by the body's extreme response to infection
- When unrecognized and untreated, sepsis leads to systemic inflammation, tissue damage and ultimately organ failure and death
- Affects more than 30 million people with six million deaths around the world each year

Procalcitonin and Sepsis

- Early diagnosis of systemic bacterial infections
- Effective monitoring of sepsis patients
- Safe antibiotic therapy guidance

TRUST IN RESULTS FOR LABORATORIES:

Reliability:
Fulfill more requests from difficult draws with small sample volume

30µL

Accuracy:
Trust your results through a quantification of endogenous interferences hemolysis, icterus and turbidity

Efficiency:
Maximize efficiency with long calibration intervals

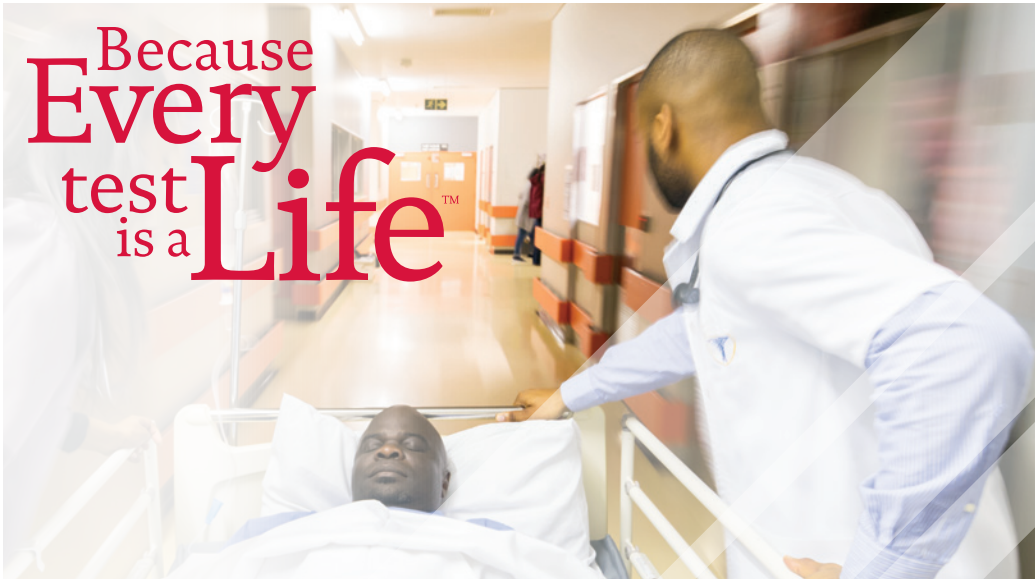
56 days

CONFIDENCE IN DECISIONS FOR CLINICIANS:

Early diagnosis of severe bacterial infections and sepsis[3-5]

Therapeutic guidance for starting and safely stopping antibiotic treatment[6,7]

Excellent analytical correlation and clinical concordance to B·R·A·H·M·S method



Procalcitonin is the best biomarker for early bacterial infection diagnosis and antibiotic stewardship[4-8]

VITROS B·R·A·H·M·S PCT assay delivers:

- **High analytical sensitivity and specificity**[1]
- **Results** that are ready to be delivered to a clinicians with 96.5% First Pass Yield (without user intervention)[2]
- **Analytical performance:** LOD at 0.007 ng/mL, LOQ (20% CV, observed) at 0.013 ng/mL
- **Fast turnaround time:** 24 minutes to first result
- **VITROS B·R·A·H·M·S PCT Assay is the reliable solution**

VITROS® B·R·A·H·M·S PCT

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:

≤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 >2.00 ng/mL

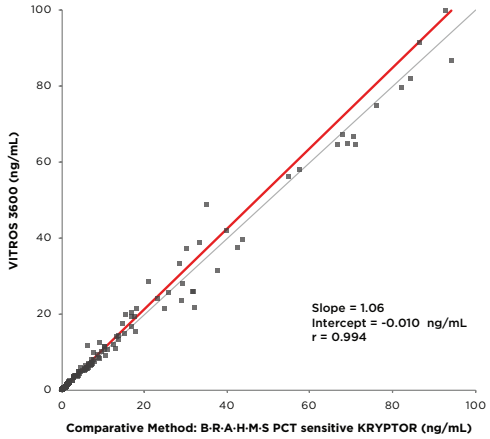
Calibration interval: 56 days

VITROS System to System correlation: within <3.7%

Not impacted by biotin interference

Excellent Analytical Correlation

Analytical correlation between VITROS B·R·A·H·M·S PCT and B·R·A·H·M·S PCT sensitive KRYPTOR



Excellent Clinical Concordance

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

0.100 ng/mL	98.5%
0.250 ng/mL	98.0%
0.500 ng/mL	97.4%
2.00 ng/mL	97.8%
10.0 ng/mL	98.0%

INTENDED USE

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

Indicated for use with the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

PRODUCT INFORMATION

ITEM	CATALOG NO.
VITROS Immunodiagnostic Products B·R·A·H·M·S PCT Reagent	690 5558
VITROS Immunodiagnostic Products B·R·A·H·M·S PCT Calibrator Pack	690 5559
VITROS Immunodiagnostic Products B·R·A·H·M·S PCT Controls Tri-Level	690 5560

References

1. Ortho Clinical Diagnostics (2020). VITROS Immunodiagnostics Products B·R·A·H·M·S PCT Reagent Pack and Calibrators Instructions For Use. Pub. No. GEM1370_XUS_EN version 2.0.
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3. Harbarth S, Holeckova K, Froidevaux C et al. Diagnostic value of procalcitonin, interleukin-6, and interlukin-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. *CID* 2004, 39(2): 206-217.