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 where the body overreacts to an 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

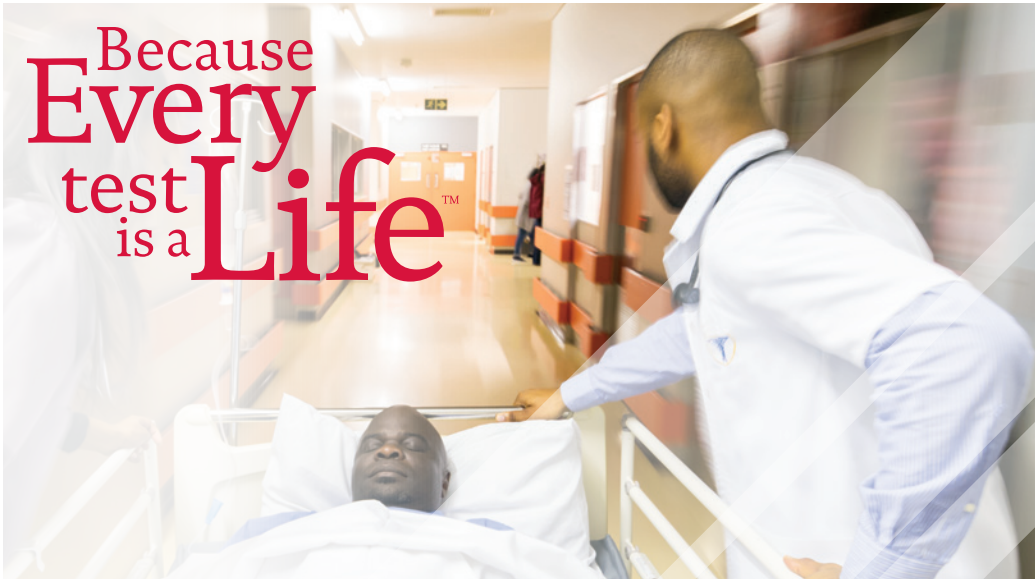
56 days

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



B·R·A·H·M·S PCT is the best biomarker for early bacterial infection diagnosis and antibiotic stewardship[4-8]

- **High sensitivity and specificity for bacterial infection enables therapeutic decision making**[3,4,5,8]
- **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:** not impacted by biotin interference

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 (within lab):

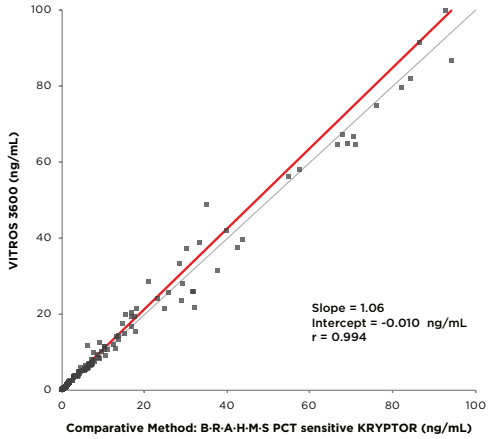
<3.9% at 0.100 ng/mL
<3.5% at 0.250 ng/mL
<3.7% at 0.500 ng/mL
<4.0% at 2.00 ng/mL
<4.1% at 10 ng/mL

Calibration interval: 56 days

VITROS System to System correlation: within <3.7%

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 risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock
- assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time
- decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department
- decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

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

PRODUCT INFORMATION

ITEM
VITROS Immunodiagnostic Products B·R·A·H·M·S PCT Reagent
B·R·A·H·M·S PCT Calibrator Pack
B·R·A·H·M·S PCT Controls Tri-Level
B·R·A·H·M·S PCT Range Verifiers

References

1. Ortho Clinical Diagnostics (2020). VITROS Immunodiagnostics Products B·R·A·H·M·S PCT Reagent Pack and Calibrators Instructions For Use. IFU PCT GEM1370_US_EN 690 5558. 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 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.