VITROS® Immunodiagnostic Products B•R•A•H•M•S Procalcitonin (PCT) Assay

For Laboratorians: Trust in Results

- **Excellent analytical performance**: LOD at 0.007 ng/mL, LOQ (20% CV) at 0.013 ng/mL
- **Fast turnaround time**: 24 minutes to first result
- **Results** that are ready to be delivered to a clinician without user intervention 96.5% of the time
- **Less workload, better efficiency**: Long calibration interval of 56 days reduces waste and maintenance time
- **98.5% system availability** with easy-to-replace parts and no water system
- **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 Assay provides robust, reliable performance** even for samples with marked hemolysis

For Clinicians: Confidence In Decisions

- **Large body of evidence** supporting clinical utility of PCT in sepsis management protocols and antibiotic stewardship
- **PCT provides therapeutic guidance** for starting and safely stopping antibiotic treatment in patients with sepsis
- **Excellent analytical correlation** to BRAHMS method
- **Excellent clinical concordance** to BRAHMS method at all diagnostic cutoffs

PCT is the best biomarker for early bacterial infection diagnosis and antibiotic guidance

- Early diagnosis of severe bacterial infections and sepsis is possible as PCT levels rise quickly after bacterial infection
- High sensitivity and specificity for bacterial infection enables therapeutic decision making
- PCT levels correlate with the patient's clinical condition, allowing effective monitoring and therapeutic guidance of sepsis patients

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.
VITROS® Immunodiagnostic Products B•R•A•H•M•S Procalcitonin (PCT) Assay

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 between VITROS and BRAHMS methods

Part of the Comprehensive VITROS Acute Care Menu

High Sensitivity Troponin I, NT-proBNP II, PCT, Nephrocheck, D-Dimer, Creatinine, ßHCG, CRP, lactate, Myoglobin, CK, CK-MB.

Not all products available in all regions or on all VITROS systems.

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>ITEM</th>
<th>CATALOG NO.</th>
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<tbody>
<tr>
<td>VITROS Immunodiagnostic Products B•R•A•H•M•S</td>
<td>690 5558</td>
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<tr>
<td>Procalcitonin Reagent</td>
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<tr>
<td>Procalcitonin Calibrator Pack</td>
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<tr>
<td>Procalcitonin Controls Tri-Level</td>
<td>690 5560</td>
</tr>
</tbody>
</table>

References

1. Ortho Clinical Diagnostics (2020). VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Reagent Pack and Calibrators Instructions For Use. GEM 1370 XUS EN. REF 690 5558. Raritan, NJ USA.