Ortho Clinical Diagnostics

VITROS® B•R•A•H•M•S PCT (Procalcitonin) Assay from Ortho Clinical Diagnostics Receives FDA 510(k) Clearance

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Ortho Clinical Diagnostics, a global leader of in vitro diagnostics dedicated to improving and saving lives through innovative laboratory solutions, received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its VITROS® B•R•A•H•M•S PCT (Procalcitonin) assay to help clinicians identify sepsis and other severe bacterial infections. Ortho's newest assay will be available in the coming weeks on the VITROS ® 3600 Immunodiagnostic System, VITROS® 5600 and VITROS® XT 7600 Integrated Systems and VITROS® ECi/ECiQ Systems.

Sepsis is a life-threatening clinical condition caused by the body's extreme response to infection. [1] If unrecognized or untreated, it can lead to systemic inflammation, tissue damage and organ failure or death.[2] Sepsis is estimated to affect more than 30 million people globally each year, potentially leading to six million deaths.[1]

Fast diagnosis and appropriate antimicrobial therapy is required to increase the likelihood of survival,[3] and multiple clinical studies recognize PCT's role in detecting severe bacterial infections and guiding the use of antimicrobial therapy. [4]

The VITROS® B•R•A•H•M•S PCT assay can aid clinical assessment in the early detection of severe bacterial infections (sepsis, community-acquired pneumonia, acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease) and in making decisions regarding antibiotic therapy.[5] Emerging antibiotic resistance has made it extremely important to reduce the unnecessary and prolonged use of antibiotics.[6]

Laboratories running the NEW VITROS B•R•A•H•M•S PCT assay leverage both the power of B•R•A•H•M•S and the difference that only VITROS ® analyzers can provide. Paired together, these VITROS® Solutions help improve patient outcomes by delivering consistently Fast, Accurate and Reliable results to the clinicians who diagnose, monitor and provide treatment. Given this VITROS benefit, labs can fulfill more requests from difficult draws with the assay's small sample size at 30µL. Further, the assay maximizes efficiency with a long calibration interval of 56 days and offers excellent analytical correlation and clinical concordance to the B•R•A•H•M•S method. [7]

> ***"When minutes matter in emergency and critical care situations, fast, accurate results determine treatment and can mean the difference between life and death," said Andy Greenfeld, Ortho's global marketing director, Clinical Labs. "Because Every Test Is a Life, Ortho Clinical Diagnostics is committed to providing medical teams with high-quality diagnostics that deliver accurate results that help clinicians treat their patients faster."***

VITROS technology ensures results are ready to be delivered to clinicians quickly, with a 96.5% first pass yield (without user intervention). Proprietary MicroSensor™ technology detects and flags results with potential hemolysis, icterus and turbidity interferences, reducing the need for reviews/reruns/redraws.[5] With a guaranteed uptime of 98%, these solutions improve a lab's ability to deliver better patient outcomes. [8]

Self-contained, waterless VITROS® Systems help ensure results are not impacted by water quality and go hand-in-hand with Ortho's goal to support long-term environmental sustainability.

1. https://www.who.int/news-room/fact-sheets/detail/sepsis

2. https://www.who.int/news-room/fact-sheets/detail/sepsis

3. https://www.ncbi.nlm.nih.gov/pubmed/30648993

4. DOI 10.1007/s00134-017-4683-6

5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3301797/

6. DOI 10.1186/s12916-017-0795-7

7. IFU PCT GEM1370_US_EN 690 5558

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