

LETTER TO THE EDITOR

Analytical Performance of the VIDAS® BRAHMS Procalcitonin Assay and Beckman Coulter Unicel® DXI Procalcitonin Assay in a Stat Laboratory

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SUMMARY

Background: The objective of this study was to compare the validity of two different procalcitonin assays.

Methods: We collected 63 plasma samples from a stat laboratory. The plasma values of procalcitonin ranged from 0.01 to 98.1 µg/L when tested on the Access® platform and from < 0.05 to 98.5 µg/L when tested on the VIDAS® platform. The patients included 28 females ranging in age from 8 to 98 years of age (68 ± 22.6 years) and 35 males ranging in age from 35 to 90 years of age (69.2 ± 13.4 years).

Results: In this study, the agreement between the two methods was good and Pearson's correlation coefficient (r) was 0.989 (p < 0.001).

Conclusions: In summary, a high correlation exists between quantitative procalcitonin measurements conducted with the VIDAS® BRAHMS and the Beckman Coulter Unicel® DXI assays. The VIDAS® BRAHMS procalcitonin assay is a reliable method for determining the levels of procalcitonin in plasma, but requires manual operation, hands-on technical expertise, and time. On the other hand, the Beckman Coulter Unicel® DXI assay is fully automated and may increase laboratory efficiency, and reduce the overall turnaround time.

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KEY WORDS

VIDAS® BRAHMS Procalcitonin, Beckman Coulter Unicel® DXI Procalcitonin

TO THE EDITOR

Sepsis is defined as a serious illness caused by a systemic inflammatory response to infection. Procalcitonin (PCT) is a protein precursor of calcitonin [1], and its concentration is a marker of severe bacterial infections and has also been approved for the management of anti-microbial therapies in patients with respiratory infection and sepsis [2-5]. PCT levels are associated with the severity of microbial invasion in patients with bacterial infections. Serum PCT levels rise more rapidly than C-reactive protein levels and peak within a very short time. PCT has been found to be superior to CRP in terms of

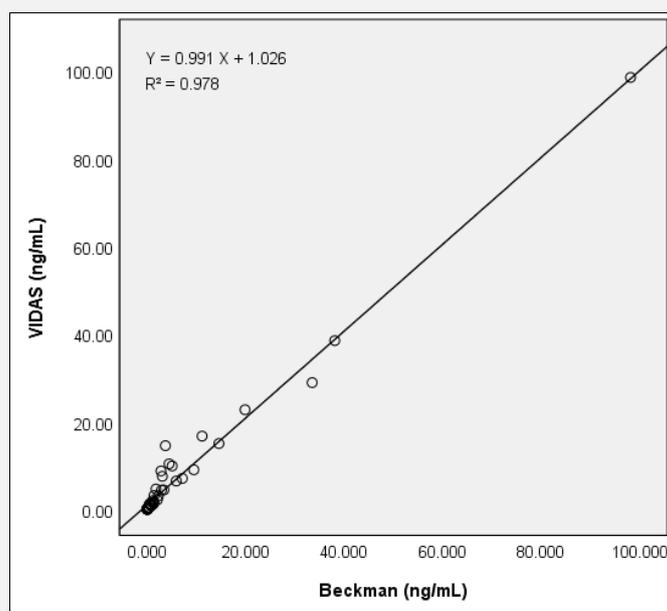


Figure 1. Comparisons of the two methods of procalcitonin measurement using Pearson's correlation coefficient.

accuracy in identifying and assessing sepsis severity [6]. In addition, sepsis is associated with significant morbidity and mortality in critically ill patients [7]. Burkhardt O et al. demonstrated that PCT monitoring can reduce the use of antibiotics in patients with acute respiratory infection [8]. Overall, PCT is an ideal diagnostic and prognostic biomarker in patients with systemic bacterial infections and decreases antimicrobial therapy requirements. Therefore, we need to provide prompt, accurate, and reliable results for physicians. In this study, we aimed to compare the validity of two different PCT assays.

The levels of plasma PCT were analyzed using the VIDAS® BRAHMS PCT assay and the Beckman Coulter Unicel® DXI PCT assay, which have reported ranges of 0.05 - 200 µg/L and 0.01 - 100 µg/L, respectively. The limit of detection using the VIDAS® BRAHMS PCT assay and the Beckman Coulter Unicel® DXI PCT assay is 0.002 µg/L, respectively. The open reagent pack and the calibration curve of the VIDAS® BRAHMS PCT assay and the Beckman Coulter Unicel® DXI PCT assay are stable for 28 days and 42 days, respectively.

In this study, we collected 63 plasma samples from the stat laboratory of Asia University Hospital and measured the plasma values of PCT, which ranged from 0.01 to 98.1 µg/L on the Access® assay and from < 0.05 to 98.5 µg/L on the VIDAS® assay. All plasma samples were anticoagulated with lithium heparin. The patients from whom these plasma samples were collected in-

cluded 28 females ranging in age from 8 to 98 years (68 ± 22.6 years) and 35 males ranging in age from 35 to 90 years (67.2 ± 13.4 years). The plasma samples were stored at -20°C after PCT measurement using the VIDAS® BRAHMS PCT assay. The two methods were compared via Pearson's correlation analysis. Figure 1 shows Pearson's correlation coefficient between the PCT levels from the two assays. The PCT levels determined with the VIDAS® BRAHMS PCT assay were correlated with the PCT levels obtained with the Beckman Coulter Unicel® DXI PCT assays, resulting in a Pearson's correlation coefficient of 0.989 ($p < 0.001$). Our results are consistent with those of a previous study, where the PCT levels determined with the VIDAS® BRAHMS PCT assays were correlated with the PCT levels obtained with the Beckman Coulter Unicel® DXI PCT assays, resulting in a correlation coefficient of 0.994 ($p < 0.001$). The authors reported acceptable correlations among 10 commercial PCT immunoassays, but limited agreement at clinical decision thresholds remains a major concern [9]. Notably, that the VIDAS® BRAHMS PCT assay showed a positive result of 14.6 µg/L; however, the Beckman Coulter Unicel® DXI PCT assay showed a positive result of 3.75 µg/L. The difference between the two assays may be affected by transport or storage conditions. As previously described [10], the inclusion of PCT in therapeutic guidelines of bacterial infections effectively and safely reduces unnecessary administration of antibiotics and the duration of antibiotic treatment. Therefore, a slightly low level of

PCT may influence clinical decision-making regarding the administration of antibiotics and the duration of antibiotic treatment.

As previously described, PCT determination can be a useful tool for diagnosing sepsis and can also be used to guide antibiotic therapy. Laboratory findings provide an essential contribution to clinical decision-making in many infectious diseases [11]. Notably, Lippi G et al. [12] showed that increased PCT values are associated with a nearly 5-fold increased risk of severe coronavirus disease 2019 (COVID-19) infection; however, the putative bacterial origin of PCT elevation in patients with severe COVID-19 must be clarified in the near future. In summary, this study demonstrates that the VIDAS® BRAHMS PCT assay is a reliable and effective approach to determine the plasma levels of PCT. However, the VIDAS® BRAHMS PCT assay is manually operated and requires hands-on technical expertise as well as time. Possible integration of the VIDAS® BRAHMS PCT assay into an automated workflow remains a large challenge that must be overcome in the near future. The development of this automated workflow is essential, as laboratories need an instrument with high capability, reliability, throughput, and sensitivity to produce accurate, reliable, and timely patient test results, especially during threats or outbreaks.

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Declaration of Interest:

There are no conflicts of interest associated with this paper.

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