Detection of Procalcitonin (PCT) in Healthy Controls and Patients with Local Infection by a Sensitive ILMA

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SUMMARY

Background: Procalcitonin (PCT) is an established marker for severe systemic bacterial infection and sepsis. So far the relevance of PCT in healthy individuals or patients with local infections is unclear due to the lack of highly sensitive assays. The aim of our study was the characterization of a new sensitive PCT assay, the establishment of reference values and the assessment of diagnostic accuracy.

Methods: We assessed PCT values in 522 patients with different infectious and non-infectious conditions and 410 healthy controls by a new coated tube sandwich chemiluminescence assay B.R.A.H.M.S ProCa-S (2 step assay, time to result 2.5 hours).

Results: The lower detection limit was 6.0 ng/L, with a functional assay sensitivity below 7 ng/L. Samples above 250 ng/L gave excellent correlation to the LUMItest PCT (r = 0.98, p < 0.0001). There was no high dose hook effect up to a concentration of 21,300 ng/L. The 410 healthy controls had a median concentration of 12.7 ng/L (95% CI: 12.6 – 14.7 ng/L). 65 controls had non-detectable PCT values (defined as 5 ng/L). The 2.5th percentile of the normal population was 5 ng/L and the 97.5th percentile was 46.7 ng/L. ROC plot analysis resulted in an area under the curve (AUC) of 0.90. The optimal decision threshold was at 50 ng/L, with a sensitivity for infection of 77.8% and a specificity of 98.5% (positive predictive value 97.7%, negative predictive value 84.9%). There was a highly significant (p < 0.0001) difference in the PCT median between healthy individuals and patients with infections (e.g. pneumonia, peritonitis) but not non-infectious controls (e.g. pregnancy, autoimmune disease).

Conclusions: The new PCT assay is 30 times more sensitive than the established routine assay LUMItest PCT, thus allowing for the first time PCT detection in healthy individuals. First results indicate that the assay is suitable to differentiate local bacterial infections from other non-infectious diseases. (Clin. Lab. 2002;48:263-270)