INTRODUCTION

Procalcitonin (PCT®) is an important diagnostic biomarker used for the diagnosis of bacterial infection and sepsis. PCT® is a prohormone for calcitonin secreted by various cell types in response to infection and inflammation. PCT® is used in a variety of settings, including primary care facilities, emergency rooms and intensive care units, where PCT® can be used to guide and monitor antibiotic treatment. PCT® serum concentration in healthy people is generally low (i.e. below 0.1 ng/mL) but is elevated in clinically relevant bacterial infections, and it continues to rise with increasing severity of the disease (Fig. 1). The LIAISON® BRAHMS PCT® II GEN uses chemiluminescent immunoassay (CLIA) technology for quantitative sensitive determination of PCT in human serum and plasma. Functional sensitivity was measured according to CLSI EP17-A at 0.04 ng/mL. The assay can be performed on both LIAISON® and LIAISON® XL platforms.

METHOD

The study was conducted on two different population in order to describe:
• the diagnostic performance of LIAISON® BRAHMS PCT® II GEN in comparison to the reference method (B·R·A·H·M·S PCT® Kryptor - Thermo Scientific Biomarkers, Germany).
• the ability of LIAISON® BRAHMS PCT® II GEN to discriminate between samples from expected healthy subjects and suspected pathological patients.

A) Prospective samples:
• 150 Apparently healthy specimens obtained from a blood bank
• 161 Hospitalized patients (for non-specific pathologies)

B) Selected samples:
193 specimens covering the assay reading range, where dose levels were already evaluated with the reference method.

RESULTS

A) Prospective samples:
The results obtained using prospective samples show (table 1):
• no samples with PCT® concentration over 0.5 ng/mL (cutoff) for the apparently healthy adults population (highest value equal to 0.033 ng/mL, 95th percentile as well as 97.5th percentile lower than 0.02 ng/mL)
• 2 samples over 0.5 ng/mL for the hospitalized patients (highest value equal to 0.715 ng/mL, 95th percentile: 0.072 ng/mL; 97.5th percentile: 0.105 ng/mL)

Table 1

<table>
<thead>
<tr>
<th>N° of samples</th>
<th>Mean dose (ng/mL)</th>
<th>95% (ng/mL)</th>
<th>97.5% (ng/mL)</th>
<th>&gt;0.5 ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy adults</td>
<td>150</td>
<td>&lt;0.020</td>
<td>&lt;0.020</td>
<td>0</td>
</tr>
<tr>
<td>Hospitalized</td>
<td>161</td>
<td>&lt;0.020</td>
<td>0.072</td>
<td>0.105</td>
</tr>
</tbody>
</table>

B) Selected samples:
The study shows excellent correlation obtained by the LIAISON® BRAHMS PCT® II GEN with B·R·A·H·M·S PCT® Kryptor both in term of slope and intercept (Fig.2) and in terms of clinical concordance as indicated below (Table 2 and Table 3)

Table 2

Table 3

CONCLUSIONS

The fully automated LIAISON® BRAHMS PCT® II GEN, with its excellent sensitivity and reproducibility should be used for early diagnosis of sepsis, severe bacterial infection of lower respiratory tract and to guide antibiotic therapy.

Main Features
• Number of tests: 100
• Platform: LIAISON® and LIAISON® XL
• Instrument: automated (CLIA)
• Assay format: Sandwich
• LoD: 0.02 ng/mL LoQ: 0.04 ng/mL
• Measuring range: 0.02 – 100 ng/mL

Quick and reliable results made possible by flexibility
• Time to 1st result: 16 minutes
• Minimum sample volume: 100 μL (plus 150 μL dead volume)
• Matrix: serum/plasma (Na citrate, EDTA, Li heparin)
• Lyophilized calibrators included in the reagent cartridge packaging
• Calibration stability: 8 weeks
• Reagent stability on board: 12 weeks