ANALYTICAL PERFORMANCE CHARACTERISTICS OF THE NEW BECKMAN COULTER ACCESS PCT IMMUNOASSAY

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BACKGROUND
Procalcitonin is a peptide of 116 amino acids with a molecular weight of ~13 kDa. PCT is produced in thyroid C-cells where it is converted to calcitonin in healthy individuals with less than 0.1 ng/mL PCT normally in circulation. PCT is a useful biomarker for diagnosis of sepsis and systemic inflammation because PCT levels increase in response to bacterial endotoxins and inflammatory cytokines. Beckman Coulter recently developed a highly sensitive procalcitonin (PCT) immunonassay for use on the Access Immunnoassay Systems. The study results described here are from prototype studies of the assay and may not represent final product claims in all geographies.

METHODS
The Access PCT assay is a sequential two-step sandwich assay. Monoclonal anti-PCT antibody alkaline phosphatase conjugate is added with sample to a reaction vessel and incubated. Paramagnetic particles coated with a different monoclonal anti-PCT antibody are then added and incubated. After washing, a chemiluminescent substrate is added and light is generated which is directly proportional to the PCT concentration in the sample. The assay time to first result is ~20 minutes.

RESULTS

Table: Analytical Performance Characteristics of the New Beckman Coulter Access PCT Immunnoassay

<table>
<thead>
<tr>
<th>Sample</th>
<th>Within-Run (Repeatability)</th>
<th>Between-Run</th>
<th>Between-Day</th>
<th>Between Lab (Total Imprecision)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>0.008 ng/mL</td>
<td>0.003 ng/mL</td>
<td>0.002 ng/mL</td>
<td>0.001 ng/mL</td>
</tr>
<tr>
<td>Sample 2</td>
<td>0.006 ng/mL</td>
<td>0.003 ng/mL</td>
<td>0.001 ng/mL</td>
<td>0.001 ng/mL</td>
</tr>
<tr>
<td>Sample 3</td>
<td>0.004 ng/mL</td>
<td>0.002 ng/mL</td>
<td>0.001 ng/mL</td>
<td>0.001 ng/mL</td>
</tr>
<tr>
<td>Sample 4</td>
<td>0.002 ng/mL</td>
<td>0.001 ng/mL</td>
<td>0.001 ng/mL</td>
<td>0.001 ng/mL</td>
</tr>
</tbody>
</table>

Figure 1: A precision study was performed according to CLSI EP05-A3 using serum samples run over 20 days. The total imprecision for serum sample mean PCT concentrations from 0.090 to 76.31 ng/mL resulted in %CV values of 3.8 to 7.2.

Figure 2: A reproducibility precision study was performed at three external sites using serum samples run in duplicate with two runs per day over five days. The reproducibility across sites for serum sample mean PCT concentrations from 0.090 to 76.31 ng/mL resulted in %CV values of 3.5 to 5.7.

Figure 3: Studies performed based on CLSI EP17-A3, the Access PCT assay exhibited a Limit of Blank of 0.001 ng/mL, and a Limit of Detection (LoD) and Limit of Quantitation (LoQ) of 0.002 ng/mL in Serum and Lithium Heparin Plasma, and 0.003 ng/mL in EDTA Plasma.

Figure 4: PCT reference interval testing was performed at one external site on an Access 2 immunoassay system using 202 serum samples from approximately equal numbers of apparently healthy male and female subjects ≥21 years of age.

Figure 5: Method Comparison with 229 patient samples using the Access PCT assay and the VIDAS B.R.A.H.M.S PCT® assay gave a Passing-Bablok Slope of 0.96 and Intercept of 0.08 ng/mL. The Pearson correlation coefficient was 0.99.

Figure 6: Method Comparison with patient samples ≤ 5 ng/mL using the Access PCT assay and the VIDAS B.R.A.H.M.S PCT® assay gave a Passing-Bablok Slope of 0.96 and Intercept of 0.08 ng/mL. The Pearson correlation coefficient was 0.99.

CONCLUSIONS
The Access PCT prototype assay is highly sensitive and precise, demonstrating strong correlation and concordance to several well-established predicate PCT methods at clinically relevant levels.

REFERENCES

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