ichromax™ PCT
Fluorescence immunoassay
Point of care test
Wide range PCT

whole blood serum plasma
ichroma™ PCT

- ichroma™ PCT along with ichroma™ Reader is a fluorescence immunoassay for quantitative determination of PCT in human sample
- PCT is known as a useful marker in the diagnosis of bacterial infection and sepsis
- Whole blood*, serum or plasma can be used as a sample. PCT testing with whole blood provides distinctive advantage in neonatal & general ICU, or emergency department for diagnosing sepsis
- Provides quantitative result in only 12 minutes with small volume of sample
- ichroma™ PCT test allows diagnosis of sepsis & bacterial infection and helps prescription decision of antibiotics

* ichroma™ PCT whole blood type will be available in early 2015.

What is Sepsis

Sepsis is whole body inflammatory state triggered by infection

<table>
<thead>
<tr>
<th>SIRS (Systemic Inflammatory Response Syndrome)</th>
<th>Systemic inflammatory response to a variety of severe clinical insults, manifested by two or more of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Temperature &gt;38°C or &lt;36°C</td>
<td></td>
</tr>
<tr>
<td>• Heart rate &gt;90 beats/min</td>
<td></td>
</tr>
<tr>
<td>• Respiratory rate &gt;20 breaths/min or PaCO₂ &lt;32 mm Hg</td>
<td></td>
</tr>
<tr>
<td>• WBC &gt;12,000/㎣, &lt;4000/㎣, or &gt;10% immature (band) forms</td>
<td></td>
</tr>
</tbody>
</table>

Sepsis

- Systemic response to infection – i.e., confirmed or suspected infection plus ≥2 SIRS criteria

Severe Sepsis

- Sepsis associated with organ dysfunction, hypoperfusion, or hypotension

Septic Shock

- Severe Sepsis that cannot be resuscitated or stabilized with IV fluids alone

Sepsis Categories

- Parasite
- Virus
- Fungus
- Bacteria
- Severe Sepsis
- Sepsis Shock
- Severe SIRS
- Trauma
- Burns

Infection

Adapted from SCCM ACCP Consensus Guidelines.

PCT test is currently the best marker for sepsis diagnosis

- PCT levels accurately differentiate sepsis from non-infectious inflammation*
- PCT has been demonstrated to be the best marker for differentiating patients with sepsis from those with systemic inflammatory reaction not related to infection.


Pros & Cons of other sepsis diagnostic tools

<table>
<thead>
<tr>
<th>Diagnostic Tool</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiology (Blood Culture)</td>
<td>Standard of care but time consuming</td>
<td></td>
</tr>
<tr>
<td>Imaging (X-Ray, Hr-CT)</td>
<td>Limitation of availability, high costs, variability of source detection</td>
<td></td>
</tr>
<tr>
<td>Molecular Biological Testing</td>
<td>Limitation of availability, costs, time consuming</td>
<td></td>
</tr>
<tr>
<td>Biopsy</td>
<td>Invasive, relatively expensive</td>
<td></td>
</tr>
<tr>
<td>C-Reactive Protein (CRP)</td>
<td>Slow kinetics, suppressed by corticosteroids, relatively inexpensive</td>
<td></td>
</tr>
</tbody>
</table>

The level of PCT can predict the severity of sepsis

Procalcitonin (PCT) values rise in relation to sepsis severity.

- In critically ill patients, PCT levels elevate in correlation to the severity of bacterial infection.
- In healthy people, PCT concentrations are found below 0.05 ng/ml.
- Concentrations exceeding 0.5 ng/ml can be interpreted as abnormal.

PCT kinetics on prognosis of sepsis patients

- Clinical symptoms alone are often insufficient for early and accurate diagnosis.
- PCT levels, can be observed within 3-6 hours after an infectious challenge with a peak up to 1,000 ng/ml after 6-12 hours. Half-life: approximately 24 hours.
- Specific to bacterial origin of infection and reflects the severity of the infection.

PCT levels elevate specifically with bacterial, but not with viral, infection.


- PCT provides a clearer picture of the patient’s response to antibiotic treatment.
- Decreasing PCT levels in patients with sepsis indicate effective treatment of the underlying infection.
- Persistently elevated PCT levels indicate a possible treatment failure.
- When integrated into the management of septic patients, PCT can help clinicians to manage septic patients more efficiently.

Stueber, F. University of Bonn, Lecture at ISICEM, Brussels 2001.

PCT guidance in antibiotic usage shorten the time patients need to be on antibiotics

PCT improves the accuracy of the early sepsis diagnosis in neonates

• In early onset neonatal sepsis PCT provides a clear differentiation of infected from uninfected neonates in the first 2 days of life.
• In neonates, the PCT values physiologically increased in relation to their age.
• A peak is reached at 24 hrs. with median at 2 ng/ml and 95% at 20 ng/ml.
• The adult reference range applies from 3 days after birth.

Normal range in neonates
(including 95% of all measurements)

<table>
<thead>
<tr>
<th>Age in hours</th>
<th>PCT[ng/ml]</th>
<th>Age in hours</th>
<th>PCT[ng/ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>2</td>
<td>30-36</td>
<td>15</td>
</tr>
<tr>
<td>6-12</td>
<td>8</td>
<td>36-42</td>
<td>8</td>
</tr>
<tr>
<td>12-18</td>
<td>15</td>
<td>42-48</td>
<td>2</td>
</tr>
<tr>
<td>18-30</td>
<td>21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adding PCT test improves the accuracy of the early clinical diagnosis of infection post organ transplant

• PCT plasma concentrations in 16 patients without postoperative complications after liver transplantation, Tx: day of transplantation.


• PCT used in early detection of infection after liver transplantation-differentiation from rejection.

Kuse ER et al., Crit Care Med 2000; 28: 555-559.
ichroma™ PCT is available on
ichroma™, ichroma™ D, ichroma™ SMART

For sales queries, please email us to PCT@boditech.co.kr

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnai-meon, Chuncheon-si, Gang-won-do, 200-883, Republic of KOREA
Tel +82-33-243-1427  Fax +82-33-243-9373
sales@boditech.co.kr

Boditech Med Europe
25a Hampstead Hill Gardens London NW32PJ, United Kingdom
Tel +44-207-947-5400  Fax +44-207-947-5401

ichroma™ SMART