from diagnosis, the seeds of better health

EMERGENCY

Reveal the picture.
Optimize your diagnosis.

NT-proBNP

from diagnosis, the seeds of better health

BIO MéRieux
NT-proBNP
A useful tool to improve diagnosis of Congestive Heart Failure

Heart failure is a common and highly disabling clinical syndrome. It is a complex and progressive clinical condition that can result from any structural or functional cardiac disorder that impairs the ‘pumping function’ of the heart.

Early and accurate diagnosis of patients presenting with dyspnea at the Emergency Department (ED) is key to initiate timely, appropriate treatment and improve patient outcome.
In establishing accurate early diagnosis or discrimination of heart failure of dyspneic patients, the measurement of B-type natriuretic peptides (NT-proBNP) leads to appropriate treatment and cost savings.

NT-proBNP A proven Marker for Heart Failure

- NT-proBNP is the N-terminal 76 amino-acid cleavage product of pro-BNP that is released from cardiac ventricles in response to increased wall stress and volume overload.
- Longer half life in the circulation (120 minutes) compared with the C-terminal BNP peptide (20 minutes), increases specimen stability for easier handling and more robust results.
- Wide dynamic range of NT-proBNP values enables accurate detection of early stages and mild forms of heart failure (1).
- Allows accurate diagnosis of heart failure in patients with dyspnea (2, 3).
- Provides prognostic information in patients with dyspnea with or without heart failure (4, 5).
- Cost-effective tool in the management of ED patients with dyspnea (Table 1) (5).

Table 1. NT-proBNP is cost-effective in the diagnosis and management of dyspneic patients in the emergency room (5)

<table>
<thead>
<tr>
<th>Criterion</th>
<th>NT-proBNP</th>
<th>Usual care</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median duration of ED visit (hours)</td>
<td>5.6</td>
<td>6.3</td>
<td>0.031</td>
</tr>
<tr>
<td>Patients re-hospitalized within 60 days (N)</td>
<td>33</td>
<td>51</td>
<td>0.046</td>
</tr>
<tr>
<td>Total direct medical costs per patient (USD)</td>
<td>$5180</td>
<td>$6129</td>
<td>0.023</td>
</tr>
</tbody>
</table>
Technical performance

Correlation with Elecsys (Roche Diagnostics)

609 samples tested using the VIDAS NT-proBNP (Y) method were compared with ELECSYS® proBNP (X) method. The following results were obtained (Passing & Bablok method and coefficient of correlation).

Precision study

Five samples were tested in duplicate in 40 different runs (2 runs per day) with 2 reagent lots at 3 sites (n=240). The repeatability (intra-run precision), inter-site reproducibility and inter-lot reproducibility were calculated using this protocol, based on the recommendations of the CLSI® EP5-A2 document:

Clinical performance

■ VIDAS NT-proBNP levels increase with disease severity as assessed by the degree of functional limitation (see figure below).

VIDAS NT-proBNP and severity of heart failure

■ High sensitivity and specificity for heart failure when used with the recommended age-dependent threshold value (see table below).

Accuracy of VIDAS NT-proBNP for the diagnosis of heart failure

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean concentration pg/mL</th>
<th>Standard deviation</th>
<th>CV (%)</th>
<th>Standard deviation</th>
<th>CV (%)</th>
<th>Standard deviation</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>116.9</td>
<td>2.8</td>
<td>2.4</td>
<td>5.1</td>
<td>4.4</td>
<td>6.3</td>
<td>5.4</td>
</tr>
<tr>
<td>C2</td>
<td>513.5</td>
<td>8.3</td>
<td>1.6</td>
<td>18.8</td>
<td>3.7</td>
<td>21.4</td>
<td>4.2</td>
</tr>
<tr>
<td>C3</td>
<td>1066.8</td>
<td>16.4</td>
<td>1.5</td>
<td>35.7</td>
<td>3.4</td>
<td>37.8</td>
<td>3.5</td>
</tr>
<tr>
<td>C4</td>
<td>714.3</td>
<td>179.0</td>
<td>2.5</td>
<td>278.4</td>
<td>3.9</td>
<td>599.8</td>
<td>8.4</td>
</tr>
<tr>
<td>C5</td>
<td>14528.6</td>
<td>408.5</td>
<td>2.8</td>
<td>743.5</td>
<td>5.1</td>
<td>1083.2</td>
<td>7.5</td>
</tr>
</tbody>
</table>
**Ease-of-use:** just load and go

**Reliable system:** MTBF over 2 years

**Cost effective:** Single-dose test, run only the test you need

**Random access**

**Quality results:** ELISA methodology

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**ITEM** | **DESCRIPTION**
---|---
Code | PBPN
Reference | 30449-01
Test/Kit | 60
Sample type | Plasma or serum
Sample volume | 200 µL
Stability of the reagent | Until expiration date
Shell life | 12 months
Calibration | 2 levels of 2 mL included in the kit, calibration verification done every 28 days
Control | 2 levels of 2 mL, included in the kit
Dilute in the kit | Yes
Measuring range | 20 - 25,000 pg/mL
Traceability | ROCHE ELECSYS® NT-proBNP
Time to result | 20 minutes
Protocol compatibility | VIDAS B•R•A•H•M•S PCT, Troponin I Ultra
Expected values | 125 pg/mL for patients < 75 years old
| 450 pg/mL for patients > 75 years old

**Detection Limits (based on CLSI EP17-A)**

- 5.4% at 116.9 pg/mL
- 4.2% at 513.5 pg/mL
- 3.5% at 1066.6 pg/mL
- 8.4% at 7143.7 pg/mL
- 7.5% at 14528.6 pg/mL
- 3.5% at 1066.6 pg/mL


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A Solution Adapted to Emergency Situations

- Large menu for emergency testing:
  - **Cardiac:** Troponin I (Ultra), CK-MB, NT-proBNP
  - **Thrombosis:** D-Dimer (Exclusion)
  - **Infections:** Procalcitonin
  - **Others:** Digoxin, hCG.