Triage BNP Test

For the Beckman Coulter Access Family of Immunoassay Systems.
The Triage BNP Test is intended for use with the Beckman Coulter Access Family of Immunoassay Systems for the *in vitro* quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant.

**The Triage BNP Test**
The Triage BNP Test is a rapid, quantitative test for the measurement of BNP. The test is used to:
- Aid in the diagnosis of heart failure
- Assess heart failure disease severity
- Risk-stratify patients with acute coronary syndromes
- Risk-stratify patients with heart failure

**Interpretation of Results**
The Beckman Coulter Access Family of Immunoassay Systems calculates the test results automatically. A number in pg/mL represents the amount of BNP present in the sample.

- BNP results ≤100 pg/mL are representative of normal values in patients without CHF.
- BNP results greater than 100 pg/mL are considered abnormal and suggestive of patients with CHF.
- BNP results ≥80 pg/mL measured in the first 72 hours after the onset of ACS symptoms are associated with an increased risk of death, myocardial infarction, and CHF.
- BNP results in HF patients indicate for every 100 pg/mL increase in BNP concentration, there is a 35% increase in the relative risk of death.
- BNP concentrations in HF patients that do not decrease from hospital admission to discharge indicate an increased risk of adverse events.
- **Pre-discharge BNP** results of 350-700 pg/mL indicate a hazard ratio of 5.1 for death or readmission for heart failure within 6 months.
- **Pre-discharge BNP** results >700 pg/mL indicate a hazard ratio of 15.2 for the same endpoint compared to patients with a pre-discharge BNP concentration <350 pg/mL.
- BNP results >5000 pg/mL are considered very high values for BNP and exceed the upper limits of the BNP test.
Clinical sensitivity and specificity.

Triage BNP Test using a cut-off of 100 pg/mL for various age groups within each gender is described below:

<table>
<thead>
<tr>
<th>Age</th>
<th>Sensitivity</th>
<th>95% Confidence Interval</th>
<th>Specificity</th>
<th>95% Confidence Interval</th>
<th>Males</th>
<th>Sensitivity</th>
<th>95% Confidence Interval</th>
<th>Specificity</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;45</td>
<td>81.6%</td>
<td>70.8-92.5%</td>
<td>98.9%</td>
<td>97.4-100.0%</td>
<td></td>
<td>82.1%</td>
<td>68.0-96.3%</td>
<td>100.0%</td>
<td>100.0-100.0%</td>
</tr>
<tr>
<td>45-54</td>
<td>76.0%</td>
<td>67.5-84.6%</td>
<td>99.5%</td>
<td>98.5-100.0%</td>
<td></td>
<td>69.0%</td>
<td>57.1-80.9%</td>
<td>98.9%</td>
<td>97.5-100.0%</td>
</tr>
<tr>
<td>55-64</td>
<td>75.6%</td>
<td>68.2-82.9%</td>
<td>98.3%</td>
<td>97.7-98.9%</td>
<td></td>
<td>82.4</td>
<td>71.9-92.8%</td>
<td>96.4%</td>
<td>95.5-97.4%</td>
</tr>
<tr>
<td>65-74</td>
<td>79.3%</td>
<td>72.6-86%</td>
<td>98.9%</td>
<td>98.4-99.4%</td>
<td></td>
<td>97.9%</td>
<td>93.7-100.0%</td>
<td>95.0%</td>
<td>93.4-96.7%</td>
</tr>
<tr>
<td>75+</td>
<td>82.4%</td>
<td>76.1-88.7%</td>
<td>95.8%</td>
<td>94.7-96.9%</td>
<td></td>
<td>91.9%</td>
<td>85.2-98.7%</td>
<td>75.7%</td>
<td>72.2-79.2%</td>
</tr>
</tbody>
</table>

Assessment of the severity of CHF.

The New York Heart Association (NYHA) developed a four-stage functional classification system for CHF that is based on a subjective interpretation of the severity of a patient's clinical signs and symptoms.

An analysis of NYHA classification and BNP concentrations from the clinical study data indicate that there is a relationship between the severity of the clinical signs and symptoms of CHF and BNP concentration.

Performance Characteristics.

Performance characteristics were determined using the Access immunoassay platform.

- **Analytical Sensitivity:** 1 pg/mL (95% confidence)
  (The lowest detectable level of BNP distinguishable from zero).
- **General Specificity:** 98%, using threshold of 100 pg/mL in the non-CHF population age 55 and older 95% confidence limit of BNP concentration
- **Total imprecision:** <7%
Ordering information

<table>
<thead>
<tr>
<th>Materials Required</th>
<th>Cat. #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triage BNP Reagents</td>
<td>98200</td>
<td>100 determinations (2 packs, 50 tests/pack)</td>
</tr>
<tr>
<td>Triage BNP QC Controls</td>
<td>98201</td>
<td>6 vials (2.5 mL/vial, 2 vials each level) Provided at approximately 80, 400 and 2,000 pg/mL</td>
</tr>
<tr>
<td>Triage BNP Calibrators</td>
<td>98202</td>
<td>6 vials (6 x 1.5 mL) S0–S5 1.5 mL/vial Provided at zero, and approximately 25, 100, 500, 2,500 and 5,000 pg/mL</td>
</tr>
</tbody>
</table>

Other materials required:
Access Substrate, Access Wash Buffer II,
One of the following Beckman Coulter immunoassay systems (Access, Access 2, Synchron LXi 725, UniCel DxC 660i, UniCel DxC 680i, UniCel DxC 860i, UniCel DxC 880i, UniCel DxI 600, UniCel DxI 800 or UniCel DxC600i)


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