IB10 sphingotest® Shortness of Breath

The assay for the in vitro quantitative determination of Cardiac Troponin I (cTnI), N-terminal pro-brain natriuretic peptide (NT-proBNP) and D-Dimer


IB10 sphingotest® Shortness of Breath is a rapid point-of-care (POC) immunoassay for the in vitro quantitative determination of Cardiac Troponin I (cTnI), N-terminal pro-brain natriuretic peptide (NT-proBNP) and D-Dimer in Lithium-Heparin human whole blood and plasma.

The test is designed for professional use only and may be used on sites where near patient testing is practiced.

- Quantitative Results
- Whole blood application
- Fast and fully automated – calibration via QR-code, no additional tests necessary
- Long-term storage at 2-8°C, 30 days stability at room temperature
- Measured on Nexus IB10 analyzer, a portable POC instrument
- Ideal for decentralized hospital facilities, acute care units and physicians practices

Clinical Significance

Simultaneous measurements of TnI, NT-proBNP and D-Dimer provide complementary (synergistic) information that aids physicians in making informed decisions for diagnosis, prognosis and treatment of both Acute Coronary Syndrome (ACS) and Heart Failure (HF) 1,2,3.

IB10 sphingotest® Shortness of Breath is intended as an aid in the differential diagnosis and prognostic assessment of patients with symptoms of chest pain, typically accompanied by respiratory distress. Individually or in conjunction with each other, these markers: aid in the diagnosis of myocardial infarction (MI), aid in the risk stratification of patients with acute coronary syndrome (ACS) including prediction of the likelihood of developing heart failure (HF), aid in the diagnosis, assessment of severity and likelihood of survival in HF, and aid in determining the probability of rule-out of patients presenting with clinical symptoms of venous thromboembolism (VTE) including pulmonary embolism (PE) and deep vein thrombosis (DVT).

Easy Handling

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>Lithium-Heparin whole blood or plasma samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIME TO RESULT</td>
<td>20 minutes</td>
</tr>
<tr>
<td>MEASURING RANGE</td>
<td></td>
</tr>
<tr>
<td>cTnI</td>
<td>0.05 – 30 ng/mL</td>
</tr>
<tr>
<td>NT-proBNP</td>
<td>30 – 5000 pg/mL</td>
</tr>
<tr>
<td>D-Dimer</td>
<td>100 – 4000 ng/mL</td>
</tr>
</tbody>
</table>

LIMIT OF DETECTION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>cTnI</td>
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<td>NT-proBNP</td>
<td>30 pg/mL</td>
</tr>
<tr>
<td>D-Dimer</td>
<td>100 ng/mL</td>
</tr>
</tbody>
</table>

NO HIGH DOSE HOOK

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>cTnI</td>
<td>up to 500 ng/mL</td>
</tr>
<tr>
<td>NT-proBNP</td>
<td>up to 300,000 pg/mL</td>
</tr>
<tr>
<td>D-Dimer</td>
<td>up to 40,000 ng/mL</td>
</tr>
</tbody>
</table>
Method Comparison

Correlation between IB10 sphingotest® Shortness of Breath and Ortho Clinical Diagnostics VITROS Troponin I ES, Roche Cobas e411 NT-proNTP and Cobas Integra D-Dimer.

**cTnI**
- IB10 = 0.80 (95% C.I. = [0.72-0.87])
- VITROS = 0.002 ng/mL

**NT-proBNP**
- IB10 = 0.97 (95% C.I. = [0.93-1.00])
- Cobas e411 = 1.182 pg/mL

**D-Dimer**
- IB10 (FEU ng/mL) = 1.20 (95% C.I. = [1.10-1.28])
- Cobas Integra = 83.04 ng/mL

Whole Blood vs. Plasma Comparison

A comparison study was performed using whole blood and plasma samples. Using a Passing-Bablok regression analysis comparing the whole blood (WB) concentrations vs. the corresponding plasma concentrations (PL) from the same subject samples, the following relationships were determined:

**cTnI**
- WB = 1.00 (95% C.I. = [0.93-1.07]) PL + 0.01 ng/mL

**NT-proBNP**
- WB = 1.107 (95% C.I. = [0.94-1.31]) PL + 5.20 pg/mL

**D-Dimer**
- WB = 1.03 (95% C.I. = [0.979-1.087]) PL - 9.1 ng/mL

Outstanding Precision

**REPRODUCIBILITY**

<table>
<thead>
<tr>
<th>Marker/Example</th>
<th>Mean Level</th>
<th>Total Precision CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>cTnI</strong></td>
<td>1</td>
<td>0.46 ng/mL</td>
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<tr>
<td></td>
<td>2</td>
<td>4.43 ng/mL</td>
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<tr>
<td><strong>NT-proBNP</strong></td>
<td>1</td>
<td>130.07 pg/mL</td>
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<tr>
<td></td>
<td>2</td>
<td>1615.8 pg/mL</td>
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<tr>
<td><strong>D-Dimer</strong></td>
<td>1</td>
<td>452.6 mIU/mL</td>
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<tr>
<td></td>
<td>2</td>
<td>843.9 mIU/mL</td>
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</table>

**EXPECTED VALUES**

**Upper Reference Limit - cTnI**

From a population of 224 individuals, IB10 sphingotest® Shortness of Breath Panel Test was used to determine the concentration upper reference limit of cTnI. This population included apparently healthy individuals.

The 99th percentile upper reference limit is 0.10 ng/mL.

**Products**

**CATALOG NUMBER**

**DESCRIPTION**

- **IVR-IB65**: IB10 sphingotest® PCT Procalcitonin (package of 10 discs)
- **IVR-IB62**: IB10 sphingotest® penKid® Proenkephalin (package of 10 discs)
- **IVR-IB58**: IB10 sphingotest® DPP3 Dipeptidyl Peptidase 3 (package of 10 discs)
- **IVR-IB56**: IB10 sphingotest® NT-proBNP NT-proBNP (package of 10 discs)
- **IVR-IB55**: IB10 sphingotest® TSH TSH (package of 10 discs)
- **IVR-IB54**: IB10 sphingotest® beta-hCG beta-hCG | package of 10 discs)
- **IVR-IB53**: IB10 sphingotest® Shortness of Breath D-Dimer, NT-proBNP, Troponin I (package of 10 discs)
- **IVR-IB52**: IB10 sphingotest® D-Dimer D-Dimer (package of 10 discs)
- **IVR-IB51**: IB10 sphingotest® 3-in-1 Cardiac Troponin I, CKMB, Myoglobin (package of 10 discs)
- **IVR-IB50**: IB10 sphingotest® Troponin-99 Troponin I (package of 10 discs)

**EXPECTED VALUES**

**Recommended Decision Threshold Values – NT-proBNP**

From calibration based on the reference Roche Elecsys® proBNP assay as measured on both the Roche Elecsys and the Ortho VITROS® Immunodiagnostic Systems, the recommended Decision Threshold Values for the IB10 sphingotest® Shortness of Breath (NT-proBNP) are:

- Patients under 75 years of age: 125 pg/mL
- Patients 75 years of age and older: 450 pg/mL

**Upper Reference Limit – D-Dimer**

From a population of 244 individuals, IB10 Shortness of Breath Panel Test was used to determine the concentration upper reference limit of D-dimer. This population included apparently healthy individuals. The 95th percentile upper reference limit, using lithium heparin as anticoagulant, is 446.8 FEU ng/mL.

**References**

