**Fast. Simple. Accurate.**

**IB10 sphingotest® Troponin-99** is a rapid point-of-care (POC) immunoassay for the *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in Lithium-Heparin 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**

cTnI determination aids in the diagnosis of myocardial infarction (MI) and patients with non-ST-segment elevation (NSTEMI) acute coronary syndrome (ACS). Elevated cTnI levels in the NSTEMI ACS subpopulation correlate with the relative risk of mortality, MI or increased probability of ischemic events requiring urgent revascularization procedures.

For patients with chronic or acute decompensated HF, measurements of cTnI provide complementary information to assist in patient evaluation and management.

**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>0.05 – 30 ng/mL</td>
</tr>
<tr>
<td>LIMIT OF DETECTION</td>
<td>0.05 ng/mL</td>
</tr>
<tr>
<td>NO HIGH DOSE HOOK EFFECT</td>
<td>500 ng/mL</td>
</tr>
</tbody>
</table>
Method Comparison

Correlation between IB10 sphingotest® Troponin-99 and Ortho Clinical Diagnostics VITROS Troponin I ES.

![Graph showing correlation between IB10 sphingotest® Troponin-99 and Ortho Clinical Diagnostics VITROS Troponin I ES.](image)

Whole Blood vs. Plasma Comparison

Passing-Bablok regression analysis comparing the whole blood concentrations vs. the corresponding plasma concentrations from the same subject samples:

\[ \text{Lithium-HeparinWB} = 1.00 \text{ Plasma (95% C.I. = [0.93-1.07]) + 0.01 ng/mL} \]

Outstanding Precision

<table>
<thead>
<tr>
<th>Sample/Marker</th>
<th>Mean Level (ng/mL)</th>
<th>Total Precision - CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.46</td>
<td>12.6</td>
</tr>
<tr>
<td>2</td>
<td>0.95</td>
<td>13.0</td>
</tr>
<tr>
<td>3</td>
<td>4.43</td>
<td>10.1</td>
</tr>
</tbody>
</table>

EXPECTED VALUES

From a population of 224 individuals, the IB10 sphingotest® Troponin-99 Test was used to determine the concentration upper reference limits of cTnI. This population included apparently healthy individuals.

Upper Reference Limit - cTnI

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

Each laboratory should establish a reference range that represents the patient population that is to be evaluated at their facility.

Products

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
</table>
| 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® Cardiac 3-in-1  
Troponin I, CKMB, Myoglobin (package of 10 discs) |
| IVR-IB50       | IB10 sphingotest® Troponin-99  
Troponin I (package of 10 discs) |

All IB10 sphingotest® test discs are CE-IVD marked.

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If you have any questions please contact your local distributor.