cobas h 232 POC system
Facilitate your clinical decisions with rapid results
Thanks to its small, portable design, the cobas h 232 POC system can be easily deployed near the point of patient care where space is tight, be it at the bedside, in triage bays or a designated lab area. The instrument is intended to be used in emergency care settings or CCU for patients presenting with acute chest pain, dyspnea and other symptoms suggestive of acute cardiovascular diseases. Studies have proven the effectiveness of cardiac marker testing with the cobas h 232 POC system in physician office settings, in particular where the use of NT-proBNP is supporting the diagnosis and assessment of heart failure. The system can also be used in pre-hospital settings like ambulances or helicopters.

The cobas h 232 POC system fits to:
• Emergency department
• Intensive care unit
• Physician’s office
• Patient’s home visits by a physician
• Ambulance
• Outpatient settings
• Remote emergencies

Examples of expertise in action
• Troponin T in chest pain – the ‘Gold Standard’ biomarker whose detection is a strong indicator of myocardial damage
• Myoglobin/CK-MB in chest pain – two biomarkers with diagnostic potential (re-infarction) early after the onset of symptoms
• NT-proBNP in dyspnea – now widely used, this biomarker can improve the diagnostic accuracy of acute heart failure in patients presenting with ambiguous or confusing symptoms
• D-dimer in venous thromboembolism – a reliable and sensitive biomarker for the exclusion of PE or DVT diagnosis in symptomatic outpatients
“Vein to Brain” in less than 15 minutes

Simple three step testing for rapid results

1. Insert strip
2. Apply sample
3. Read the result

Using the cobas h 232 POC system a blood sample can be analyzed on the spot and accurate results will be delivered in only 15 minutes.

“The next decade will undoubtedly see a vibrant co-evolution of cardiac biomarkers and POC testing as the vanguard of cardiac diagnostics”

McDonnell, B., et al., Clinical Biochemistry 2009

[Image of a cobas h 232 POC system with instructions: Insert strip, Apply sample, Read the result]
Point of Care (POC) improves turnaround time

Comparison of POC and central laboratory turnaround times (TAT) in cardiac markers
The overall gain in time from POC testing compared with central laboratory measurements was 65 minutes (range 34-135 minutes).7

The National Academy of Clinical Biochemistry guidelines recommend:

- “the laboratory should perform cardiac marker testing with a turnaround time (TAT) of 60 minutes, optimally 30 minutes or less. The TAT is defined as the time from blood collection to the reporting of results.”6

- “Institutions that cannot consistently deliver cardiac TATs of one hour or less should implement POC testing devices.”6
**cobas h 232 POC system**

*Facilitate your clinical decisions with rapid results*

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**cobas h 232 POC system realizes POC benefits**
- Enables fast patient stratification
- Accelerates moving patients to the right place
- Ensures valuable resources are focused on those patients who need it the most
- Cost-effective due to improvements in workflow

**cobas h 232 POC system is easy to use**
- No sample preparation
- Automatic calibration
- No complicated setup procedures: intuitive, icon-based interface
- Maintenance-free

**cobas h 232 POC system is highly versatile**
- Lightweight, compact and portable: the instrument can be moved once the test strip has fully absorbed the sample
- Stand alone or connected to IT system
- Configurable software for individual needs
- Easy handling thanks to intuitive user guidance

**cobas h 232 POC system is reliable**
- Roche CARDIAC assays are validated by clinical studies and comparable to Roche laboratory methods (allowing seamless follow-up testing)
- Use of patient and user ID allows to properly document test results
Enhanced expert analysis and expertise

Rapid results delivered by the cobas h 232 POC system can augment the decision process and clarify next steps
- Helps to rule in and to identify the critically ill patient
- Enables prioritization of those patients for whom early intervention is critical
- Confirmatory diagnosis avoids unnecessary referral to ICU
- Gives comfort to your patients and the family members by reassurance

The capabilities of the cobas h 232 POC system can be further enhanced when connected to the comprehensive cobas IT 1000 data management system
- Additional functions e.g. remote set up, patient and operator lists
- Electronic storage of test results in central patient record
- Controlled access to cobas h 232 POC system only for trained and certified operators supports quality results and avoids unmonitored overuse
- Connection to other data management solutions and the HIS/LIS
References
7. Gaze, D. et al. (2004). The Use of a quantitative Point of Care system greatly reduces the turnaround time of cardiac marker determination. Point of Care; 3(4): 156-158.
Improved features of the cobas h 232 POC system

New software release

New features at a glance

- New dialog function
- Improved usability of certain functionality
- Early warning of TnT elevation
- New features with cobas IT 1000 – Hidden List
- New features with cobas IT 1000 – OTS (observed test sequence)
Improved features of the cobas h 232 POC system

New software release

New dialog function

Improved error message display:
• Error reference number
• Clear error description
• Suggested steps to correct the error

Improved information display:
• Reference number of information message
• Clear information message
• Suggested next steps

Improved usability of certain functionality

Improved main menu:
• Increased space between “Patient Test” button and others ensures quicker test access
• New position of time and date display matches POC standard

Improved “Patient Test - Result” window:
• Bigger font size emphasizes the most important information
• Up to three independent comments can be added by typing or selecting from a pre-stored list
• New “Scan” button allows reactivation of the scanner when entering operator or patient ID – no need to restart test if batch is not scanned within 10 seconds

Early warning of TnT elevation

Improved early TnT alert functionality:
• Changed threshold from 100ng/L to 50ng/L when this limit is reached during the measurement
• Changed display from “TnT Positive” to “TnT Elevated”
New features with cobas IT 1000 – Hidden List

Select Operator ID
- None
- List
- Hidden List

Select Patient ID
- Off
- Optional
- Required
- Hidden List

Operator ID “Hidden List”:
- Operator verification before instrument use – especially useful if operators are not required to use a password
- Added security offered by the combination of password and “Hidden List”

Patient ID “Hidden List”:
- Prevents test assignment to a random patient
- Entry of patient ID required before test start
- Patient ID matched against patients on the “Hidden List”

New features with cobas IT 1000 – OTS (observed test sequence) supported with cobas IT 1000 V2.01

Step 1: Patient tests marked with “trainee operator” symbol require OTS

Step 2: A designated supervisor observes every step

Step 3: Supervisor’s approval is granted only when the operator passes the OTS
Restandardized Roche CARDIAC T Quantitative
For consistency between lab and Point of Care

Restandardized Roche CARDIAC T Quantitative – standardized against Elecsys cTnT-hs

**Same test strip (unchanged)**
- cTnT from blood reacts with antibodies on the strip and being localized on the capturing line
- Signal intensity (of the capturing line) is being quantified by the **cobas h** 232 POC system as reflectance value (raw unit of the instrument, not displayed to the user)
- For the same sample the reflectance value remains the same before and after the re-standardization
- Strip does not contain standardization information
- Strip test does not change clinical performance, sensitivity and stability

**Different code chip (changed)**
- Standardized against Elecsys cTnT-hs
- Chip contains standardization information and new calibration curve
- cTnT concentration is being calculated by the **cobas h** 232 POC system based on calibration curve from code chip and measured reflectance value
- One reflectance value can get different concentration values and units assigned, depending on the lot-specific calibration curve

Restandardized Roche CARDIAC T Quantitative – the units change from ng/mL to ng/L (= pg/mL) to be consistent with Elecsys cTnT-hs

**cTnT old standardization**

**OLD calibration curve:**
Lowest reflectance value assigned to **0.03 ng/mL** - matching same numbers on Elecsys TnT 4th generation instruments

**cTnT new standardization**

**NEW calibration curve:**
Lowest reflectance value assigned to **50 ng/L (= pg/mL)** - matching same numbers and unit on Elecsys cTnT-hs instruments
Restandardized Roche CARDIAC T Quantitative

For consistency between lab and Point of Care

Restandardized Roche CARDIAC T Quantitative – comparable reported results with Elecsys cTnT-hs*

<table>
<thead>
<tr>
<th>TnT value measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs (ng/L)</th>
<th>TnT value measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-4th gen. STAT (ng/mL)</th>
<th>TnT value displayed on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.03</td>
<td>51</td>
<td>Trop T 50-100 ng/L</td>
</tr>
<tr>
<td>0.05</td>
<td>70</td>
<td>Trop T 116 ng/L</td>
</tr>
<tr>
<td>0.08</td>
<td>97</td>
<td>Trop T 242 ng/L</td>
</tr>
<tr>
<td>0.10</td>
<td>116</td>
<td>Trop T 1,748 ng/L</td>
</tr>
<tr>
<td>0.25</td>
<td>242</td>
<td>Trop T &gt; 2,000 ng/L</td>
</tr>
<tr>
<td>2.0</td>
<td>1,748</td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td>2,245</td>
<td></td>
</tr>
</tbody>
</table>

* Data on file

Restandardized Roche CARDIAC T Quantitative – consistent results between lab and Point of Care

The figures below show method comparisons between 3 lots of Roche CARDIAC T Quantitative and Roche Elecsys TnT-hs: results of 5 sites based upon 148-159 evaluable pairs of values.¹

![Graphs showing method comparisons](image)

P/B Regression

- **Lot 280272-10, HVB**
  - Trop T [ng/L] measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs.
  - Reference: Y = 0.88 * X + 2.3
  - N = 154, r = 0.96

- **Lot 280308-10, HVB**
  - Trop T [ng/L] measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs.
  - Reference: Y = 0.86 * X + 15.7
  - N = 159, r = 0.95

- **Lot 280309-10, HVB**
  - Trop T [ng/L] measured on cobas h 232 POC system with the Roche CARDIAC T Quantitative test standardized against Elecsys cTnT-hs.
  - Reference: Y = 0.89 * X + 4.0
  - N = 157, r = 0.95

The results demonstrate the reliability of the calibration of the assay and the good concordance with the laboratory reference.

References


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Switzerland
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## cobas h 232 POC system

### Product specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Material order no</th>
<th>Dimensions (mm)</th>
<th>Screen</th>
<th>Power supply</th>
<th>Connectivity</th>
<th>Cut-off/Reference range</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobas h 232 POC system</td>
<td>04 901 126 190</td>
<td>L 275</td>
<td>Touch screen 78x58 mm</td>
<td>Input: 100-240 Volt/50-60Hz/400mA</td>
<td>Infrared data port enables data transfer to optional Handheld Base Unit or printer with serial infrared port</td>
<td>&lt; 50 ng/L – AMI not likely, but possible 50-100 ng/L – AMI possible; initiate treatment accordingly (re-test) &gt; 100 ng/L – AMI (very) likely; initiate treatment accordingly</td>
</tr>
<tr>
<td>cobas h 232 POC system</td>
<td>04 901 142 190</td>
<td>L 275</td>
<td>Touch screen 78x58 mm</td>
<td>Output: 75 Volt/1.7A</td>
<td>Infrared data port enables data transfer to optional Handheld Base Unit or printer with serial infrared port</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>W 102</td>
<td></td>
<td>CE/TÜV/VDE-GS/UL label</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>D 55</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Parameter

<table>
<thead>
<tr>
<th>Test strip</th>
<th>Material order no</th>
<th>Reaction time</th>
<th>Measuring range</th>
<th>Clinical utility</th>
<th>Cut-off/Reference range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin T</td>
<td>Roche CARDIAC T</td>
<td>12 mins</td>
<td>50-2000 ng/L</td>
<td>Diagnosis of acute coronary syndrome and myocardial infarction</td>
<td>&lt; 50 ng/L – AMI not likely, but possible 50-100 ng/L – AMI possible; initiate treatment accordingly (re-test) &gt; 100 ng/L – AMI (very) likely; initiate treatment accordingly</td>
</tr>
<tr>
<td></td>
<td>Quantitative</td>
<td></td>
<td>(quantitative range 100-2000 ng/L)</td>
<td>Diagnosis of acute coronary syndrome and myocardial infarction, assessment of re-infarction</td>
<td></td>
</tr>
<tr>
<td>CK-MB</td>
<td>Roche CARDIAC CK-MB</td>
<td>12 mins</td>
<td>1.0-40 ng/mL</td>
<td>Diagnosis of acute coronary syndrome and myocardial infarction, assessment of re-infarction</td>
<td>Female 4 ng/mL* Male 7 ng/mL*</td>
</tr>
<tr>
<td></td>
<td>04 877 772 190</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myoglobin</td>
<td>Roche CARDIAC M</td>
<td>8 mins</td>
<td>30-700 ng/mL</td>
<td>Early marker of myocardial damage to assist in diagnosis of acute coronary syndrome and myocardial infarction</td>
<td>Female 7 ng/mL - 64 ng/mL Male 16 ng/mL - 76 ng/mL</td>
</tr>
<tr>
<td></td>
<td>04 877 799 190</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-dimer</td>
<td>Roche CARDIAC D-Dimer</td>
<td>8 mins</td>
<td>0.1-4.0 μg/mL</td>
<td>Exclusion of deep vein thrombosis and pulmonary embolism</td>
<td>0.5 μg/mL</td>
</tr>
<tr>
<td></td>
<td>04 877 802 190</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NT-proBNP</td>
<td>Roche CARDIAC proBNP+</td>
<td>12 mins</td>
<td>60-9000 pg/mL</td>
<td>Aid in diagnosis of patients with suspected heart failure, in monitoring of patients with compensated left ventricular dysfunction and in risk stratification of patients with acute coronary syndromes</td>
<td>Exclusion of non-acute heart failure &lt; 125 pg/mL Exclusion of acute heart failure &lt; 300 pg/mL Consideration of age-stratified cut-points for diagnosis (= CHF likely considering confounding factors) Patient age NT-proBNP value</td>
</tr>
<tr>
<td></td>
<td>05 533 643 190</td>
<td></td>
<td></td>
<td></td>
<td>&lt; 50 &gt; 450 pg/mL 50-75 &gt; 900 pg/mL &gt; 75 &gt; 1800 pg/mL</td>
</tr>
</tbody>
</table>

* At the 99th percentile of a reference population
<table>
<thead>
<tr>
<th>Quality Controls</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche CARDIAC</td>
<td>Control set for use with Roche CARDIAC T Quantitative (control set for 2 x 6 quality control checks, level 1/2, and code chip)</td>
</tr>
<tr>
<td>Control Troponin T</td>
<td>04 890 515 190</td>
</tr>
<tr>
<td>Roche CARDIAC</td>
<td>Control set for use with Roche CARDIAC CK-MB (control set for 2 x 6 quality control checks, level 1/2, and code chip)</td>
</tr>
<tr>
<td>Control CK-MB</td>
<td>04 890 426 190</td>
</tr>
<tr>
<td>Roche CARDIAC</td>
<td>Control set for use with Roche CARDIAC M (control set for 2 x 6 quality control checks, level 1/2, and code chip)</td>
</tr>
<tr>
<td>Control Myoglobin</td>
<td>04 890 469 190</td>
</tr>
<tr>
<td>Roche CARDIAC</td>
<td>Control set for use with Roche CARDIAC D-Dimer (control set for 2 x 6 quality control checks, level 1/2, and code chip)</td>
</tr>
<tr>
<td>Control D-Dimer</td>
<td>04 890 523 190</td>
</tr>
<tr>
<td>Roche CARDIAC</td>
<td>Control set for use with Roche CARDIAC proBNP (control set for 2 x 6 quality control checks, level 1/2, and code chip)</td>
</tr>
<tr>
<td>Control proBNP</td>
<td>04 880 493 190</td>
</tr>
<tr>
<td>Roche CARDIAC</td>
<td>Reusable control strips to verify the function of the cobas h 232 POC system</td>
</tr>
<tr>
<td>IQC</td>
<td>04 880 688 190</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accessories</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche CARDIAC Pipettes</td>
<td>Dosing device for sample transfer from primary sampling tube, labelled to show required sample volume</td>
</tr>
<tr>
<td>11 622 889 190</td>
<td></td>
</tr>
<tr>
<td>Handheld Battery Pack</td>
<td>Rechargeable battery pack for up to 18 measurements</td>
</tr>
<tr>
<td>04 805 640 001</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Options</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handheld Base Unit/Connectivity Interfaces</td>
<td>Battery pack recharging. Data interface. Connectivity: USB and Ethernet port</td>
</tr>
<tr>
<td>04 805 658 001</td>
<td></td>
</tr>
<tr>
<td>IT Data Management</td>
<td>Interface to cobas IT 1000 data management solution</td>
</tr>
<tr>
<td></td>
<td>POCT1A – protocol for interfacing to cobas IT 1000 data management solution or third party systems as well as LIS/HIS</td>
</tr>
</tbody>
</table>

The cobas h 232 POC system features easy-to-use on-board data management. Through connectivity, results can be made available throughout your site. With a Point of Care data management system, data administration, control over QC and instrument configuration is enabled from a remote point e.g. the laboratory.