cobas h 232 system
When on the spot cardiac decisions need on the spot results in Primary Care
Is there a better pathway?

**Without Point of Care (POC) testing**

1. Patient presents
2. Blood sample taken
3. Lab collects sample (daily collection)
4. Sample prepared and analysed in the lab
5. Result generated (electronic or hard copy)
6. Result communicated to patient
7. Appropriate action taken

**With POC testing**

1. Patient presents
2. **POC test in only 12 minutes**
3. POC test gives on the spot result
4. Appropriate action taken
The path of least resistance

By providing rapid, accurate results near the patient, POC testing speeds up diagnosis and treatment, improving clinical outcomes and ensuring patients are managed efficiently and more cost-effectively.

“Practices should put in place models of care so that they use a systematic approach for…identifying people at high risk of CHD…(and) offering regular review to people at high risk of CHD.”

National Service Framework – Coronary Heart Disease

Practice management

- Results are available within minutes, helping to improve efficiency
- Appropriate treatment can be given without delay
- Hospital referrals can be reserved for patients who really need it1–3

Patient outcomes

- Rapid diagnosis allows appropriate treatment to be initiated by GP’s
- Early diagnosis and treatment reassures patients and reduces anxiety associated with uncertainty

Cost-effectiveness

- Early therapeutic initiation and regular monitoring can help reduce complications and improve cost-efficiency
- Avoiding unnecessary referrals to Secondary Care will save the practice money
Introducing the new cobas h 232 system

Designed for on the spot cardiac decisions

**Speed**
- Results available in 8–12 minutes
- Rapid, on-the-spot decision support for treatment, referral, or discharge of cardiovascular patients

**Portability**
- Portable device which is suitable for use in the GP’s surgery, one stop clinics or community hospitals

**Ease of use**
- Insert strip, apply sample, read result
- Intuitive touch-screen
- No maintenance
- Easy to clean

**Reliability**
- On board QC
- External QC through the provision of EQA ampoules
- Results comparable to Roche laboratory methods\(^5\)-\(^8\)
- Quality assurance via patient identification and QC operator lock-out

**Connectivity**
- Results transmitted via IR to printer or Base Unit
- In combination with cobas IT 1000 data management solution, reduces effort for documentation and fulfilment of quality assurance requirements
cobas h 232
– when you need to be sure

3 simple steps to quick results

1. Slide in test strip
2. Apply sample (150 µL heparinized whole blood)
3. Result appears on screen within minutes

<table>
<thead>
<tr>
<th>Test Strip &amp; Material Order No.</th>
<th>Parameter</th>
<th>Reaction Time</th>
<th>Measuring Range</th>
<th>Clinical Utility</th>
<th>Cut-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche CARDIAC D-Dimer 04877802 190</td>
<td>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>Roche CARDIAC proBNP 04877845 190</td>
<td>NT-proBNP</td>
<td>12 mins</td>
<td>60 – 3000 pg/mL</td>
<td>Diagnosis and assessment of congestive heart failure Risk stratification in acute coronary syndrome</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)</td>
</tr>
<tr>
<td>Roche CARDIAC T Quantitative 04877772 190</td>
<td>Troponin T</td>
<td>12 mins</td>
<td>0.03 – 2 ng/mL (quantitative range 0.1 – 2 ng/mL)</td>
<td>Diagnosis of acute coronary syndrome and myocardial infarction</td>
<td>&lt; 0.03 ng/mL – low risk 0.03 – 0.1 ng/mL – medium risk &gt; 0.1 ng/mL – high risk</td>
</tr>
<tr>
<td>Roche CARDIAC M** 04877999 190</td>
<td>Myoglobin</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>70 ng/mL</td>
</tr>
<tr>
<td>Roche CARDIAC CK-MB 04877900 190</td>
<td>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>
</tbody>
</table>

* At the 99th percentile of a reference population
** Roche CARDIAC M for use on the cobas h 232 system will be available in the course of Q3/2007
D-dimer is a specific fragment of cross-linked fibrin that circulates in the blood stream for several days following a thrombotic event, such as DVT. Patients at high risk of DVT include those receiving high dose oestrogen therapy, those who have previous history of DVT, post surgical and limited mobility.

D-dimer is produced naturally as part of the wound healing process, but can be found in higher quantities in the blood in abnormal clotting processes, as with thrombosis or embolism. When clots are formed at the wrong time and place as a result of underlying diseases, the presence of D-dimer indicates the occurrence of unwanted thrombotic events.

**Diagnostic value of D-dimer:**

- D-dimer is a valuable marker to rule out suspected DVT and PE.
- Used as first diagnostic step, the determination of D-dimer helps to avoid unnecessary and expensive examinations and therapeutic interventions
  - D-dimer based protocols can reduce treatment costs by avoiding the use of expensive imaging techniques.
**NT-proBNP**

BNP is synthesized as the prohormone proBNP and is released from the myocardium into the circulation upon myocardial stress. After stimulation of heart muscle cells, proBNP is cleaved by a protease into N-terminal proBNP (NT-proBNP) and the biologically active hormone BNP. The biological half-life of NT-proBNP is 60–120 minutes (BNP is only 20 minutes).

**Diagnostic value of NT-proBNP:**

- High negative predictive value (> 97%) enables exclusion of heart failure in symptomatic patients, allowing appropriate action to be taken.
- Helps to confirm the presence of heart failure, giving confidence to begin appropriate treatment sooner.
- An alternative assessment to Echo, reducing pressure on waiting lists.
- Sensitive test enables diagnosis of systolic and diastolic ventricular dysfunction, even in mild and asymptomatic cases of heart failure.
- Allows for risk stratification and assessment of prognosis across a wide range of cardiovascular diseases.
- Cost savings by optimising resources and decreasing the need for other diagnostic tests.

![Graph showing % reduction](image-url)
Troponin T

Cardiac troponin T is the most specific, and sensitive, biochemical marker of myocardial necrosis. A positive test result clearly establishes the diagnosis of myocardial infarction, even if symptoms or electrographic changes are ambiguous or not present.

Diagnostic value of troponin T:
- Most appropriate cardiac marker and criterion to define acute myocardial infarction, according to the ESC/ACC recommendations\textsuperscript{21,22}
- Can detect non-ST segment infarctions in patients presenting with acute coronary syndrome
- Large window of detection (2 hours up to 14 days) – an infarction can be confirmed in patients that report complaints only, after one or two weeks

Myoglobin

Myoglobin, a non cardiac specific protein in the cytoplasm of striated muscles, is rapidly released from the cells after muscle damage. Determination of myoglobin covers the early phase of myocardial infarction diagnosis since it is the first and the most sensitive biochemical marker that can be detected in the blood.

Myoglobin increases as early as 1 to 2 hours after the onset of chest pain. However, since elevated myoglobin is not specific for damage of the heart muscle, a troponin T test must be performed to confirm the diagnosis of myocardial infarction. Myocardial infarction is ruled out if myoglobin is not detected within 6 hours after onset of symptoms.\textsuperscript{23}

Diagnostic value of myoglobin:
- Earliest marker to appear \(< 2\) hours post-infarction
- Useful when the patient presents to physician very soon after onset of symptoms\textsuperscript{24}
CK-MB

Creatine kinase (CK) is an enzyme that mainly occurs in muscles, heart and brain. It is divided into three different forms: CK-MM (muscle type), CK-MB (heart-type) and CK-BB (brain-type). Total CK thus only offers limited specificity. In myocardial damage, such as in acute myocardial infarction, cardiac specific CK-MB is released from destroyed myocardial cells.

An increase of CK-MB activity in the blood can be detected as early as 2–3 hours after the infarction. CK-MB activity reaches its peak after 12–24 hours and returns to the reference range usually after 2–3 days.

Diagnostic value of CK-MB:

- Diagnosis of ACS and myocardial infarction

- CK-MB and troponin T have identical intended uses except that, due to the different kinetics with a shorter half-life (peak within 24 hours), CK-MB can be used for reinfection assessment
  - CK-MB is indicative for reinfection if level does not return to normal within approx. 2–3 days from peak, whereas troponin T is still elevated

- Can be used in combination with myoglobin and troponin T
  - for a complete assessment of cardiac markers
  - to allow alignment with existing protocols
  - when specifically indicated by the patient’s circumstances
Useful information

Websites

**NICE – National Institute for Clinical Excellence**
http://www.nice.org.uk/

**SIGN – Scottish Intercollegiate Guidelines Network**
http://www.sign.ac.uk/

**DoH Publications and Statistics**

**Cardiology Pathway**
http://www.18weeks.nhs.uk/public/

**Practice Based Commissioning**
http://www.dh.gov.uk/assetRoot/04/13/13/97/04131397.pdf

**Health Improvement Programme**
http://www.heart.nhs.uk/Health Improvement Programme

Material order numbers:

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<tr>
<td>Roche CARDIAC IQC strip</td>
<td>Reusable control strips to verify the function of the <strong>cobas h</strong> 232 analyzer</td>
</tr>
<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>Handheld Base Unit/Connectivity Interfaces</td>
<td>Battery pack recharging Data interface Connectivity: USB and Ethernet port</td>
</tr>
<tr>
<td>IT Data Management</td>
<td>Interface to <strong>cobas IT</strong> 1000 data management solution POCT1A – protocol for interfacing to <strong>cobas IT</strong> 1000 data management solution or third party systems as well as LIS/HIS</td>
</tr>
<tr>
<td>Handheld Battery Pack</td>
<td>Rechargeable battery pack for up to 10 measurements</td>
</tr>
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References
