



Rely on the cobas h 232 POC system
*On the spot cardiac marker results comparable
to the laboratory*



Comparison of all Roche cardiac tests with the reference laboratory method - excellent analytical agreement



The **cobas h 232** POC system was evaluated in a multicenter study involving 18 sites across six countries with the aim of comparing the system to the laboratory reference method for each test and verifying specifications. Three lots each of the Roche CARDIAC T Quantitative (Troponin T), Roche CARDIAC CK-MB, Roche CARDIAC M (Myoglobin), Roche CARDIAC proBNP (NT-proBNP) and Roche CARDIAC D-Dimer assays were investigated. With each lot of these

assays, whole blood samples from patients with relevant conditions such as acute coronary syndrome, congestive heart failure, or deep vein thrombosis were measured. The distribution of the samples ensured coverage of the whole measurable concentration ranges of each assay. In addition, Roche CARDIAC assay performance was compared between the cardiac reader and **cobas h 232** Point-of-Care systems.¹

Conclusions

- The **cobas h 232 POC system multicenter evaluation yielded a very good analytical agreement of all Roche CARDIAC tests with the respective comparison and reference methods.**
- **Reliable quantitative results can be easily and rapidly obtained to support on-site decision making for cardiovascular patients in critical situations in the emergency room and in the assessment of potential cardiovascular complaints in primary care.**

Study population

In total 1326 patients and 954 healthy volunteers were included in the multicenter evaluation. The numbers of patients and healthy individuals broken down to the different study arms are shown in Table 1.

Study arm	Patients	Healthy individuals
NT-proBNP	304	151
Troponin T	218	245
CK-MB	205	247
Myoglobin	316	191
D-Dimer	283	120

Table 1: Study population

Imprecision

For the evaluation of within-series imprecision heparin blood samples from patients with low, medium and high plasma concentrations of the respective analyte were used. Each sample was measured in 10 replicates with the Roche CARDIAC assays.

The median within-series CV resulting from tenfold measurements with patient samples ranged from 6 % for the Roche CARDIAC CK-MB assay to 10 % for the Roche CARDIAC D-Dimer assay (Figure 1).

Within-series imprecision of the Roche CARDIAC assays

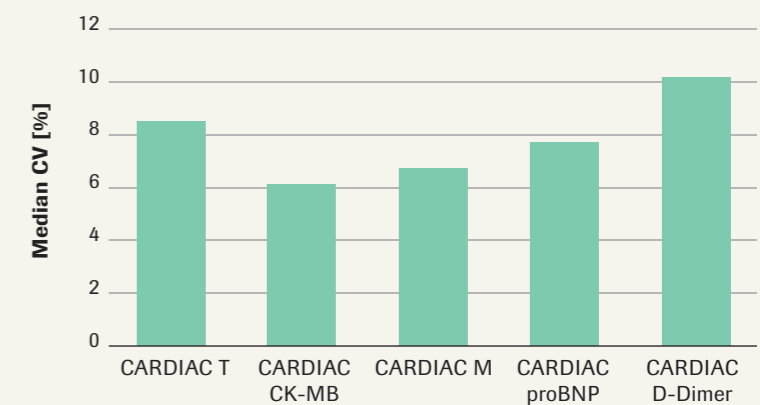


Figure 1: (n=10 repeats/series)

Series were measured with heparin blood samples from patients and healthy individuals. Median coefficients of variation (CV) of all series are shown.



Method comparisons resulted in very good agreement with the respective laboratory reference methods

In method comparisons, all three independently calibrated lots of each of the five Roche CARDIAC assays measured on the **cobas h 232** POC system showed very good agreement with the respective laboratory reference test, with median bias being mostly below 10 %, in particular in the clinically relevant ranges, and correlation coefficients above 0.91 across the board.

Roche CARDIAC proBNP assay

In method comparisons all three independently calibrated lots of the Roche CARDIAC proBNP assay measured on the **cobas h 232** POC system showed an excellent agreement with the Elecsys proBNP laboratory test. The median bias of Roche CARDIAC proBNP compared to the Elecsys proBNP assay was between 3 % and 5 %, the correlation coefficient r between 0.95 and 0.98 (Figure 2).

Method comparison Roche CARDIAC proBNP assay determined on the cobas h 232 POC system vs. Elecsys proBNP

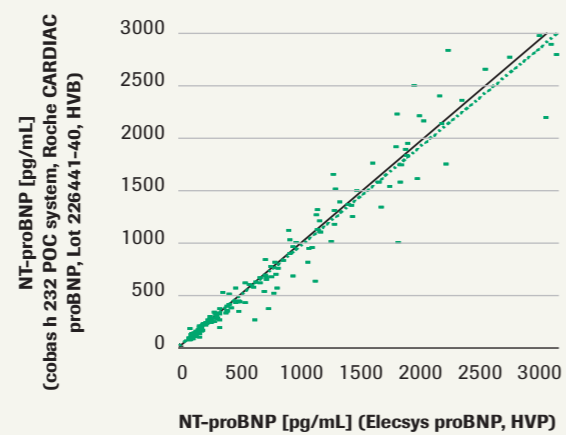


Figure 2: $Y=1.04X - 1.8$ (Passing-Bablok regression), $r=0.98$, $n=162$, HVB=heparinized venous blood, HVP=heparinized venous plasma

Roche CARDIAC T Quantitative assay

The evaluation of a Roche CARDIAC T Quantitative masterlot at six sites demonstrated an excellent agreement of the assay measured in heparin blood with the calibration method Elecsys Troponin T measured with serum. The correlation coefficient r of Roche CARDIAC T Quantitative on the **cobas h 232** POC system compared to the Elecsys Troponin T assay was 0.94, the median bias 2 % (Figure 3).

Method comparison Roche CARDIAC T Quantitative assay determined on the cobas h 232 POC system vs. Elecsys Troponin T

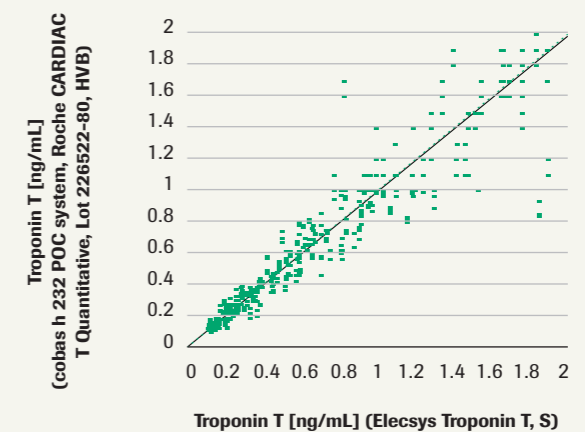


Figure 3: $Y=0.99X + 0.01$ (Passing-Bablok regression), $r=0.94$, $n=475$, HVB=heparinized venous blood, S=serum



Roche CARDIAC CK-MB assay

Three independently calibrated lots of the Roche CARDIAC CK-MB assay were in a median bias range of 0 % to 9 % compared to the Elecsys CK-MB laboratory reference method. The correlation coefficient r ranged from 0.97 to 0.99. These results demonstrated the reliability of the calibration of the test and the excellent concordance with the Elecsys CK-MB assay (Figure 4).

Method comparison Roche CARDIAC CK-MB assay determined on the cobas h 232 POC system vs. Elecsys CK-MB

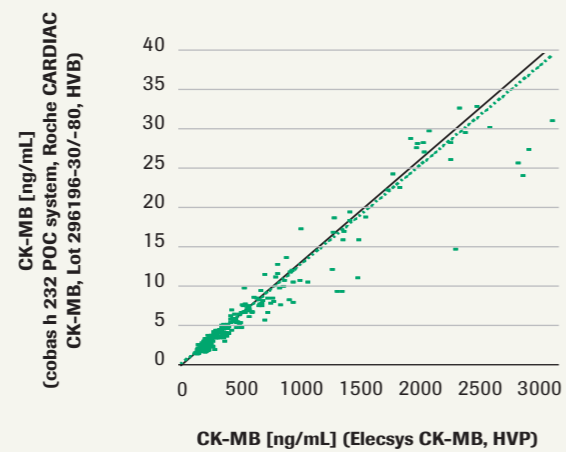


Figure 4: $Y=1.04X - 0.1$ (Passing-Bablok regression), $r=0.97$, $n=335$, HVB=heparinized venous blood, HVP=heparinized venous plasma

Roche CARDIAC M assay

In the method comparisons all lots of the Roche CARDIAC M assay measured on the **cobas h 232** POC system showed a good agreement with Tina-quant Myoglobin. The slopes of the regression lines of the combined method comparisons for all sites were between 1.00 and 1.08 and the correlation coefficients r between 0.92 and 0.96 depending on the lot used. The median relative bias values of the Roche CARDIAC M assay on the **cobas h 232** POC system compared to Tina-quant Myoglobin were between 4 % and 9 % (Figure 5).

Method comparison Roche CARDIAC M assay determined on the cobas h 232 POC system vs. Tina-quant Myoglobin

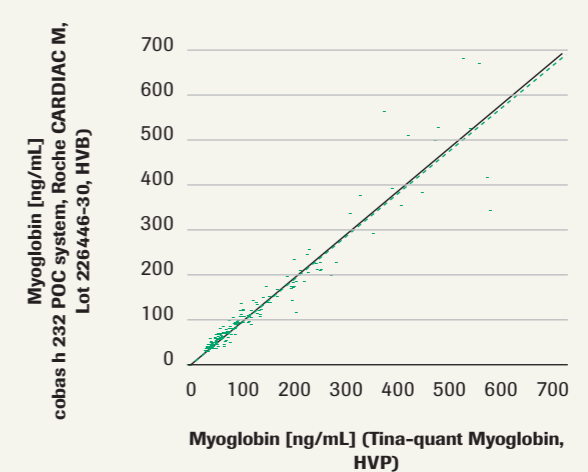


Figure 5: $Y=1.00X + 5.2$ (Passing-Bablok regression), $r=0.96$, $n=223$, HVB=heparinized venous blood, HVP=heparinized venous plasma



Instrument comparisons showed excellent agreement

Roche cardiac reader versus cobas h 232 POC system

Roche CARDIAC D-Dimer assay

In the multicenter performance evaluation of the **cobas h 232** POC system, trueness of Roche CARDIAC D-Dimer test was evaluated using three independently calibrated lots of the assay in comparison with the reference method, the Tina-quant D-Dimer assay. In these method comparisons, all lots showed a very good agreement with the Tina-quant D-Dimer reference method. The median bias in method comparisons on the **cobas h 232** POC system versus the Tina-quant D-Dimer assay was between 0 % and 7 %, the correlation coefficient r between 0.91 and 0.95 (Figure 6).

Method comparison Roche CARDIAC D-Dimer assay determined on the cobas h 232 POC system vs. Tina-quant D-Dimer

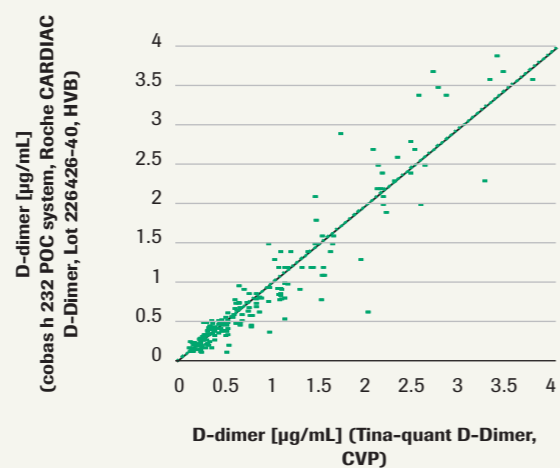


Figure 6: $Y=1.00X$ (Passing-Bablok regression), $r=0.95$, $n=188$, HVB=heparinized venous blood, CVP=citrated venous plasma

In addition, the performance of Roche CARDIAC assay lots on the **cobas h 232** POC system was compared against the performance on the Roche cardiac reader system to verify comparability of results between the two POC platforms of Roche. All three independently calibrated lots of each of the five Roche CARDIAC

assays measured on the **cobas h 232** POC system and Roche cardiac reader systems showed excellent agreement with each other, with values for the median bias of 5 % or below and correlation coefficients of 0.96 or more (Table 2).

Assay	Median relative bias [%]	Pearson's r
Roche CARDIAC proBNP	-1.0	0.98
Roche CARDIAC T Quantitative	0	0.97
Roche CARDIAC CK-MB	+2.7	0.99
Roche CARDIAC M	+2.6	0.99
Roche CARDIAC D-Dimer	+5.0	0.96

Table 2: Results of instrument comparisons Roche cardiac reader (X) versus **cobas h 232** POC system (Y). r =correlation coefficient

User study



The handling of the **cobas h 232** POC system according to 89% of all users was rather easy. A user study was carried out to assess the overall usability of the **cobas h 232** POC system in the hands of untrained users. Users involved in the multicenter evaluation were asked to rate the handling, user interface, data processing, cleaning, manual and further aspects of the system both at the start of the study and at the end on base of their experiences during the study.

The resulting assessments from before and after the study showed that the **cobas h 232** POC system was overall well-liked and easy to use, thanks in particular to the guidance provided by the user interface during the test procedure.

The general handling* of the cobas h 232 POC system

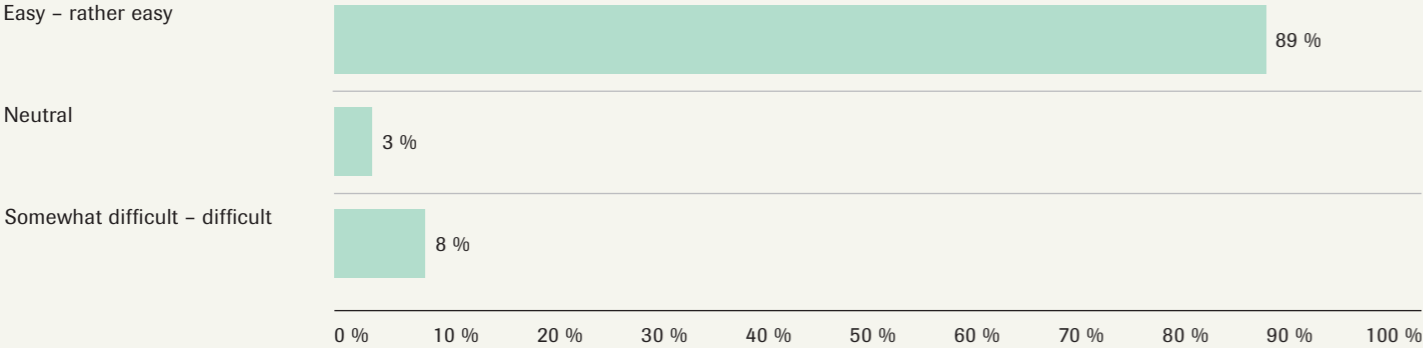


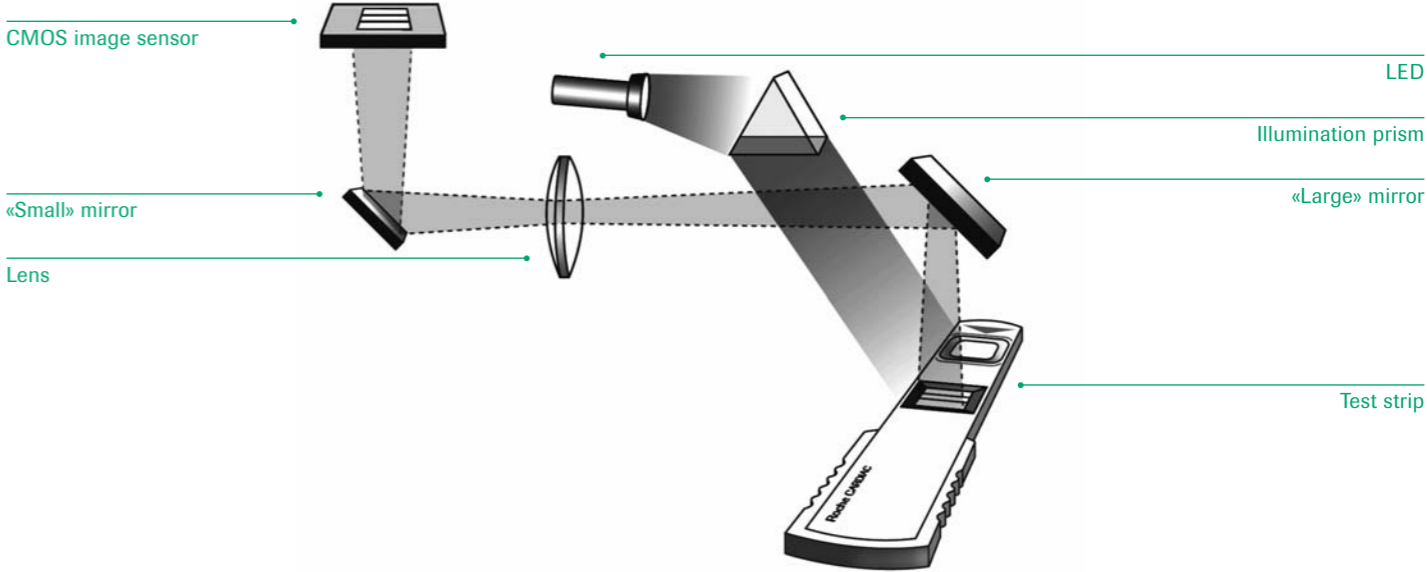
Figure 7: *General handling includes all instrument handling e.g. lot coding and QC testing

Working principle

The **cobas h 232** POC system is a portable POC device using the Roche CARDIAC assays.²⁻⁶ The test principle of these assays has been described previously.^{7,8} Like the Roche cardiac reader, the **cobas h 232** POC system optically records an image of the detection zone of the test strips via a digital camera chip (Figure 8). Signal and control lines in the detection zone of the test strip are identified by a

pattern recognition algorithm and quantified by the integrated system software. A lot-specific calibration curve supplied by the manufacturer in each test kit is used to determine the analyte concentration.^{3,8} The turnaround times for the assays are between approximately 10 and 15 minutes, the sample volumes needed are 150 µL.

Optical pathway and detection principle of the cobas h 232 POC system



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