Clin Chem Lab Med 2006;44(10):1269–1277 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.215

Multicentre evaluation of a new point-of-care test for the determination of NT-proBNP in whole blood

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Abstract

Background: The Roche CARDIAC proBNP point-of-care (POC) test is the first test intended for the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in whole blood as an aid in the diagnosis of suspected congestive heart failure, in the monitoring of patients with compensated left-ventricular dysfunction and in the risk stratification of patients with acute coronary syndromes.
Methods: A multicentre evaluation was carried out to assess the analytical performance of the POC NT-proBNP test at seven different sites.
Results: The majority of all coefficients of variation (CVs) obtained for within-series imprecision using native blood samples was below 10% for both 52 samples measured ten times and for 674 samples measured in duplicate. Using quality control material, the majority of CV values for day-to-day imprecision were below 14% for the low control level and below 13% for the high control level. In method comparisons for four lots of the POC NT-proBNP test with the laboratory reference method (Elecsys proBNP), the slope ranged from 0.93 to 1.10 and the intercept ranged from 1.8 to 6.9. The bias found between venous and arterial blood with the POC NT-proBNP method was ≤5%. All four lots of the POC NT-proBNP test investigated showed excellent agreement, with mean differences of between −5% and +4%. No significant interference was observed with lipaemic blood (triglyceride concentrations up to 6.3 mmol/L), icteric blood (bilirubin concentrations up to 582 μmol/L), haemolytic blood (haemoglobin concentrations up to 62 mg/L), biotin (up to 10 mg/L), rheumatoid factor (up to 42 IU/mL), or with 50 out of 52 standard or cardiological drugs in therapeutic concentrations. With bisoprolol and BNP, somewhat higher bias in the low NT-proBNP concentration range (<175 ng/L) was found. Haematocrit values between 28% and 58% had no influence on the test result. Interference may be caused by human anti-mouse antibodies (HAMA) types 1 and 2. No significant influence on the results with POC NT-proBNP was found using volumes of 140–165 μL. High NT-proBNP concentrations above the measuring range of the POC NT-proBNP test did not lead to false low results due to a potential high-dose hook effect.
Conclusions: The POC NT-proBNP test showed good analytical performance and excellent agreement with the laboratory method. The POC NT-proBNP assay is therefore suitable in the POC setting.
Clin Chem Lab Med 2006;44:1269–77.

Keywords: analytical performance; brain natriuretic peptide (BNP); congestive heart failure; natriuretic peptides; N-terminal proBNP (NT-proBNP); point-of-care testing.

Introduction

Chronic heart failure (CHF) is the only cardiovascular disease that is still characterised by increasing incidence and prevalence (1, 2). Therefore, accurate diagnosis and adequate management of such patients have an important impact on healthcare systems.

Consequently, the guidelines of the European Society of Cardiology recommend analysis of brain natriuretic peptide (BNP) or N-terminal proBNP (NT-proBNP), in combination with assessment of symptoms and clinical findings, electrocardiogram, chest X-ray and Doppler-echocardiography, when evaluating patients with suspected heart failure (3, 4). Numerous retrospective and prospective clinical studies have demonstrated that a wide range of clinical applications related to heart failure (and acute coronary syndromes), including diagnosis, monitoring

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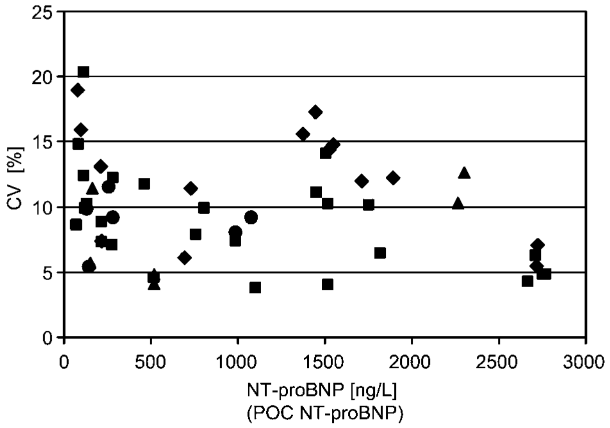

Figure 1 Within-series imprecision of POC NT-proBNP using patient samples (n=10 replicates). ■ lot 226382-30; ♦ lot 226383-30; ▲ lot 226384-30; ● lot 226396-30. CV, coefficient of variation

and prognosis, may benefit from the determination of these peptides.

NT-proBNP testing has been shown to be useful in ruling out acute heart failure in the emergency department (5–8) and to improve the diagnostic accuracy of heart failure in the primary care setting (9, 10). Plasma NT-proBNP is a powerful predictor of in-hospital and long-term mortality of patients with severe heart failure (11–16). Furthermore, a small pilot study showed that adjustment of heart failure therapy guided by serial measurements of NT-proBNP can improve outcome compared to intensive clinically guided treatment (17).

The physiologically active hormone BNP and the inactive NT-proBNP are released from the myocardium as a response to myocardial stretch. Both are cleavage products of the precursor peptide proBNP. NT-proBNP was shown to have a similar or even better correlation to left ventricular dysfunction as BNP (18). In addition, NT-proBNP is stable for up to at least 72 h after blood sampling, and has a longer half-life and consequently higher plasma levels compared to BNP (19–21).

According to the guidelines of the National Academy of Clinical Biochemistry on biomarkers of acute coronary syndrome and heart failure, BNP or NT-proBNP testing should be performed on a 24-h basis, and results should be provided with a turnaround time from blood collection within 60 min. Point-of-care testing is therefore favoured in cases for which the central laboratory cannot provide test results continuously within this time interval (22).

The cost-effectiveness of point-of-care testing has been reported with respect to length of stay in the coronary care unit (23), time to discharge from the emergency department (ED) (23) or from the hospital (24), and total treatment costs in the ED (24).

The Roche CARDIAC proBNP test (Roche Diagnostics GmbH, Mannheim, Germany) is the first point-of-care (POC) test for the determination of NT-proBNP and the fourth test developed for the Roche cardiac reader system. The test uses one monoclonal and one polyclonal antibody for the quantitative measurement of NT-proBNP in heparinised whole blood. The test principle, using a biotinylated and a gold-labelled antibody and sandwich-type detection of the analyte, is comparable to the other tests of the Roche cardiac reader system, Roche cardiac T Quantitative, Roche CARDIAC M and Roche CARDIAC D-Dimer (25–27).

The measurement range of the test is between 60 and 3000 ng/L. It is calibrated against the Elecsys proBNP comparison method using heparinised blood with the POC NT-proBNP test and heparinised plasma with the laboratory NT-proBNP test. The reaction time is approximately 12 min and the sample volume is 150 μL.

We present here the results of an analytical multicentre evaluation of the POC NT-proBNP test.

Materials and methods

Analytical methods

POC NT-proBNP measurements were performed using the Roche CARDIAC proBNP test with heparinised blood or quality control material (Roche CARDIAC Control proBNP Level Low and High; Roche Diagnostics). The instrument used was the Roche cardiac reader (Roche Diagnostics). Comparisons were made using the NT-proBNP assay on the Elecsys family of analysers (Roche Diagnostics) with heparinised plasma (20, 28, 29).

Imprecision studies

Within-series imprecision for blood samples and controls Imprecision was determined for native heparinised blood samples at four centres using 10 replicates of 52 samples. The imprecision was further determined at seven centres using 674 duplicate measurements for native heparinised blood samples and 317 and 312 duplicate measurements of the controls, with each replicate on a different instrument. All coefficients of variation (CVs) were calculated using the mean value (MV) and standard deviation (SD) for the duplicate or ten-fold series: CV, %=SD/MV×100.

Table 1 Within-series imprecision of the POC NT-proBNP method using patient blood samples or controls with four lots of POC NT-proBNP on two instruments.

Blood samples			Controls	
Concentration range, ng/L			Low level 188 ng/L[a]	High level 1188 ng/L[a]
60–125	125–3000	60–3000		
9.6 n=99 duplicates	7.8 n=575 duplicates	8.1 n=674 duplicates	7.9 n=317 duplicates	7.4 n=313 duplicates

Mean coefficients of variation (CV, %) of the duplicates are shown. [a] Mean value.

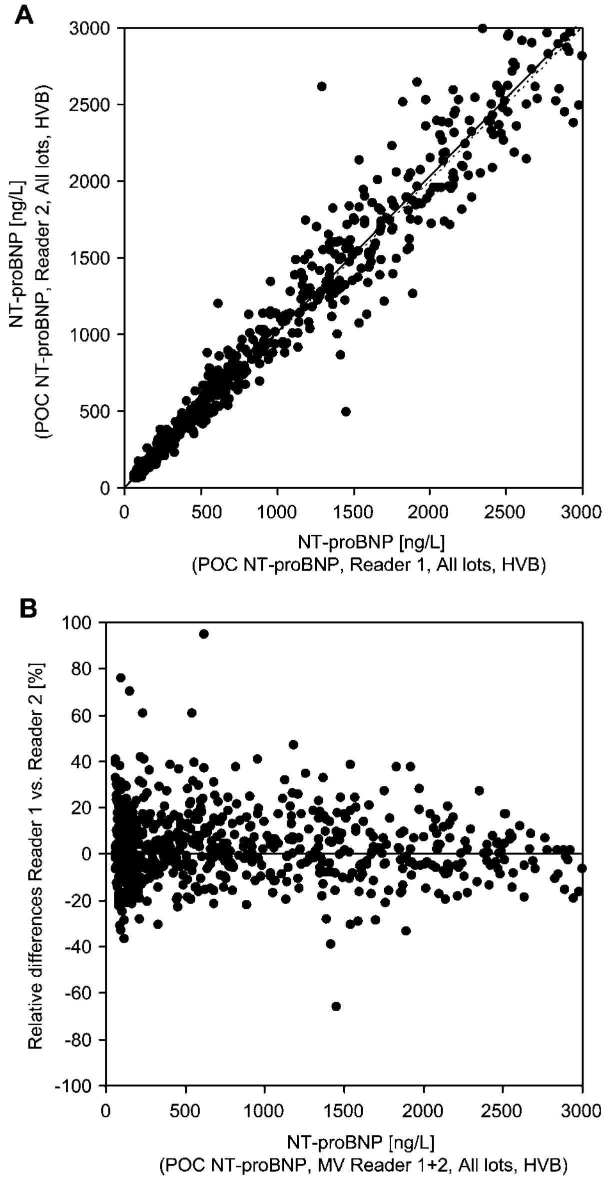

Figure 2 Comparison of duplicate measurements with two instruments: POC NT-proBNP, Reader 1, all lots, heparinised venous blood (HVB) vs. POC NT-proBNP, Reader 2, all lots, heparinised venous blood (HVB). $y=1.02x+1.6$ (Bablok-Passing regression); $r=0.98$; $n=874$. MV, mean value. (A) Regression plot and (B) Bland-Altman plot.

Day-to-day imprecision for controls Day-to-day imprecision data were obtained from daily quality control measurements for 11–39 days (one sample/day per instrument). Only evaluation centres with a 10-day measurement period or longer were considered for the data analysis. Five centres fulfilled this criterion; two did not and were disregarded. The controls were freshly reconstituted each day and were measured on each instrument.

Method comparisons with the laboratory NT-proBNP method

Comparisons between the POC and laboratory NT-proBNP methods were carried out at seven centres. A total of 420 samples from patients with suspected heart failure and 168 samples from healthy volunteers were studied. Informed consent according to the Helsinki declaration was obtained

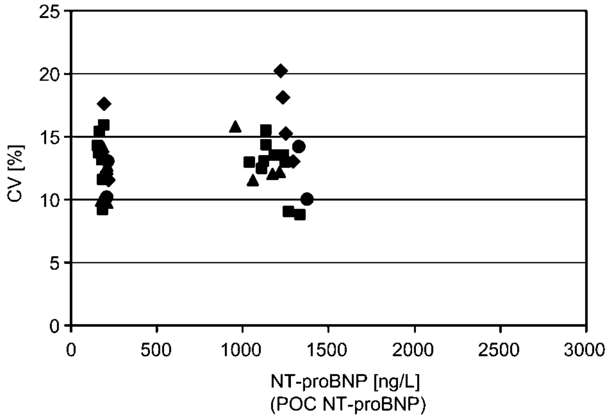

Figure 3 Day-to-day imprecision of POC NT-proBNP using system controls (n=11–39 days): ■ lot 226382-30; ◆ lot 226383-30; ▲ lot 226384-30; ● lot 226396-30. CV, coefficient of variation.

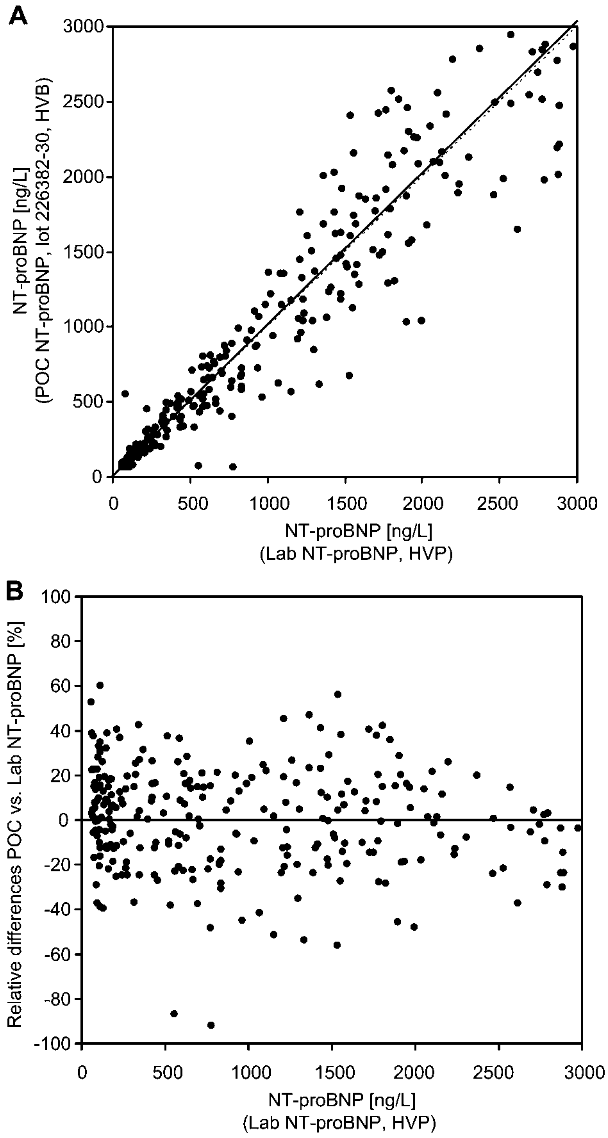

Figure 4 Method comparison with the laboratory method: POC NT-proBNP, lot 226382-30, heparinised venous blood (HVB) vs. laboratory NT-proBNP method, heparinised venous plasma (HVP). $y=1.01x+3.9$ (Bablok-Passing regression); $r=0.95$; $n=279$. (A) Regression plot and (B) Bland-Altman plot.

Table 2 Method comparisons for POC NT-proBNP (heparinised blood) vs. laboratory NT-proBNP (heparinised plasma).

x	y	n	Median bias, %	Mean bias, %	r	a	b
Lab NT-proBNP	POC NT-proBNP, lot 226382	279	1.6	3.3	0.95	3.9	1.01
Lab NT-proBNP	POC NT-proBNP, lot 226383	119	−4.7	1.7	0.94	6.9	0.93
Lab NT-proBNP	POC NT-proBNP, lot 226384	83	0.6	1.3	0.98	1.8	0.99
Lab NT-proBNP	POC NT-proBNP, lot 226396	74	11.5	7.8	0.95	5.6	1.10

Regression was calculated according to Passing and Bablok: $y=a+b\times x$, with r the correlation coefficient.

from all patients and volunteers. Venous heparinised blood samples were collected and measured with the POC NT-proBNP test within 4 h. Samples were then centrifuged and the resulting plasma samples were deep-frozen and later analysed using the laboratory NT-proBNP test in one core laboratory.

Comparison of sample materials

At two centres the performance of the POC NT-proBNP method using arterial heparinised blood was compared with that for venous heparinised blood. A total of 62 venous and arterial heparinised blood samples were collected in parallel from patients undergoing cardiac catheterisation and were assayed using the POC NT-proBNP method.

Lot-to-lot comparisons

To verify the reproducibility of the calibration, four lots of the POC NT-proBNP test were investigated using fresh heparinised venous blood collected from 420 patients with suspected heart failure and from 168 healthy volunteers.

Daily quality control

Quality control of the POC NT-proBNP test comprised daily determination of the manufacturer's controls at each centre. Quality control of the laboratory NT-proBNP test was performed with the respective package controls during each run.

Interference testing

For interference testing, heparinised blood or plasma was spiked with biotin, bilirubin, rheumatoid factor, or drugs (for concentrations see Table 4; for concentrations of the drugs see Table 5) and with NT-proBNP pool serum. The NT-proBNP pool serum was obtained from remainders of anonymised samples from dialysis patients.

To determine the potential interference of haemoglobin, patient blood samples were haemolysed by passing them multiple times through a syringe and needle. The resulting free haemoglobin concentrations in plasma were measured photometrically according to Fairbanks et al. (30). The recovery of spiked NT-proBNP concentrations before and after the haemolysis procedure was determined.

The POC NT-proBNP test uses the monoclonal antibody MAB-CK MM-M 33-IgG (MAB 33, Roche Diagnostics) as a blocking agent to avoid interference with human anti-mouse antibodies (HAMA). The influence of HAMA on POC NT-proBNP was tested by adding MAB 33 and NT-proBNP to commercial HAMA type 1 and type 2 samples (Roche Diagnostics). Interference can be excluded if the recovery of NT-proBNP in the sample does not change with increasing concentrations of the HAMA-blocking agent MAB 33.

To determine the influence of haematocrit and triglycerides, method comparisons using the samples collected from patients with suspected congestive heart failure and from healthy volunteers were carried out.

Influence of sample volume

The sample volume dependence was investigated with volumes between 135 and 165 µL. Heparinised blood samples from healthy volunteers spiked with NT-proBNP were used in these experiments.

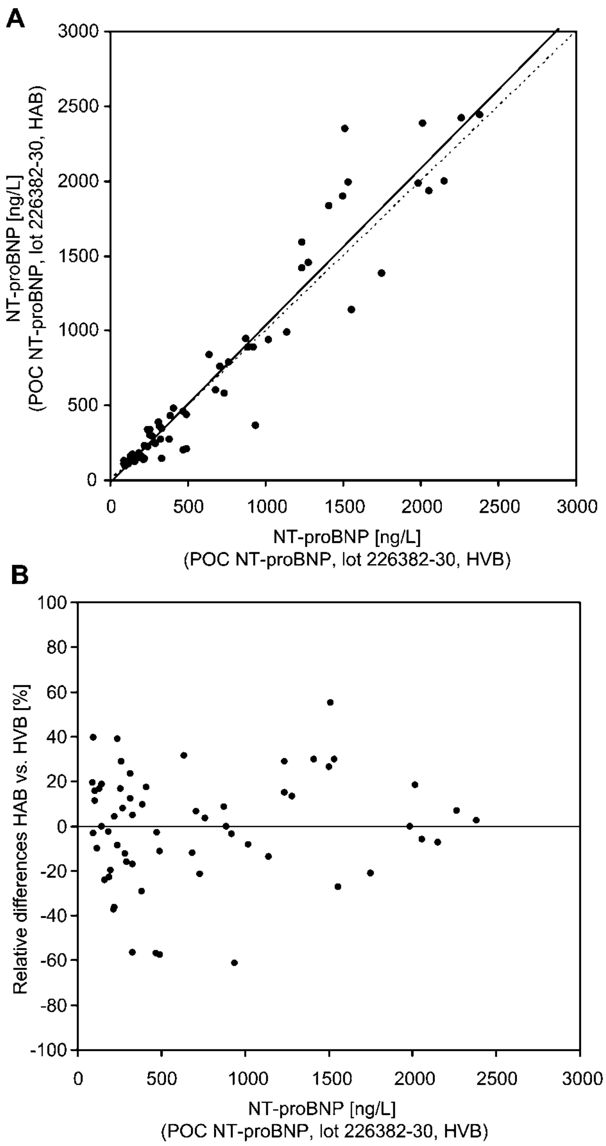

Figure 5 Comparison of sample materials: POC NT-proBNP, heparinised venous blood (HVB) vs. POC NT-proBNP, heparinised arterial blood (HAB). $y=1.05x-12.8$ (Bablok-Passing regression); $r=0.96$; $n=62$. (A) Regression plot and (B) Bland-Altman plot.

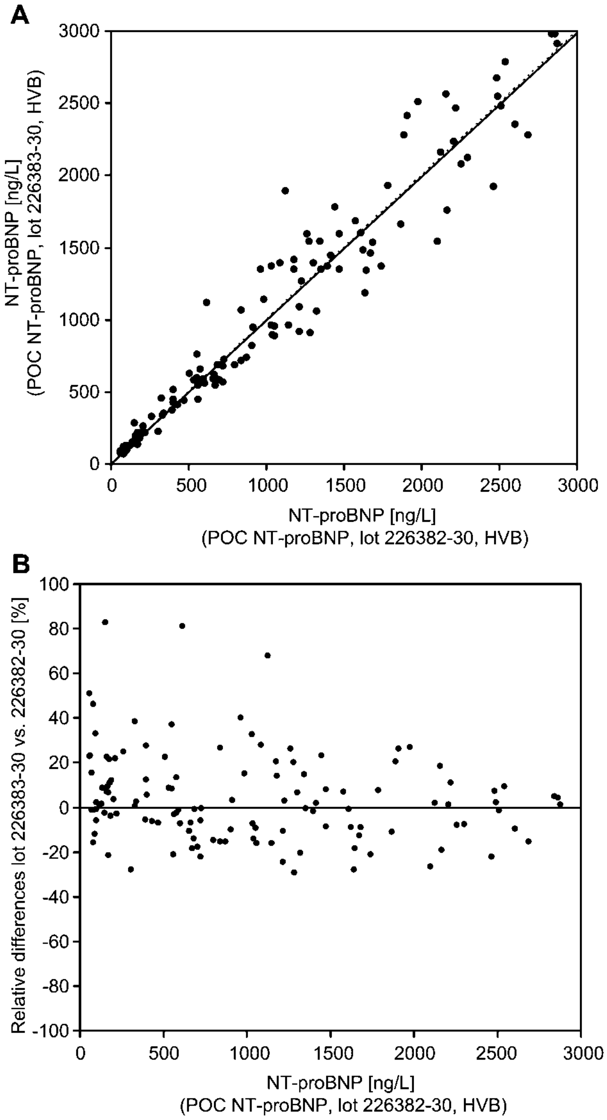

Figure 6 Lot-to-lot comparison with POC NT-proBNP. Lot 226382-30, heparinised venous blood (HVB) vs. lot 226383-30, heparinised venous blood. y=1.00x+2.6 (Bablok-Passing regression); r=0.97; n=125. (A) Regression plot and (B) Bland-Altman plot.

High-dose hook effect

Immunoassays may yield false-negative results for samples containing very high analyte concentrations. This phenomenon is called the high-dose hook effect and is caused by saturation of all antibody binding sites with antigen, preventing formation of the expected sandwich complex. In investigations into the potential high-dose hook effect, heparinised blood samples from healthy donors were spiked with NT-proBNP up to a concentration of 35,000 ng/L.

Results and discussion

Within-series imprecision for blood samples and controls

The majority of within-series CVs for 52 heparinised blood samples resulting from ten-fold measurements in the imprecision study (Figure 1), as well as the majority of within-series CVs for heparinised blood samples resulting from the 674 duplicate measurements in the method comparison, were below 10% (Table 1). A comparison of all 674 duplicate measurements between the two instruments and a Bland-Altman plot of the differences is shown in Figure 2.

The mean CVs for 317 or 313 duplicate measurements during daily quality control were 8% and 7% for the low and high POC NT-proBNP control levels, respectively (Table 1).

Day-to-day imprecision and recovery for controls

The CVs for day-to-day imprecision for the majority of samples were below 14% and 13% for the low and high POC NT-proBNP control levels, respectively (Figure 3).

For all 1276 measurements using the liquid controls, 100% were recovered within the target range given by the manufacturer.

Method comparisons with the laboratory NT-proBNP test

All lots of POC NT-proBNP showed very good agreement in method comparisons with the laboratory NT-proBNP test. The median bias compared to the laboratory NT-proBNP method was between −5% and +12% for different lots of POC NT-proBNP. The slope for method comparison of POC NT-proBNP vs. laboratory NT-proBNP ranged between 0.93 and 1.10, and the intercept ranged between 1.8 and 6.9. The correlations in these comparisons were ≥0.94 (Figure 4, Table 2).

Comparison of sample materials

There was good overall agreement between venous and arterial blood in comparisons using two lots of POC NT-proBNP. The bias found was ≤5% (Figure 5). This difference was similar to that found for the lot-to-lot comparisons (see below).

Table 3 Lot-to-lot comparison for the POC NT-proBNP method.

x	y	n	Median bias, %	Mean bias, %	r	a	b
POC NT-proBNP, lot 226382	POC NT-proBNP, lot 226383	125	1.2	4.0	0.97	2.6	1.00
POC NT-proBNP, lot 226382	POC NT-proBNP, lot 226384	88	−1.7	−1.3	0.99	8.7	0.95
POC NT-proBNP, lot 226382	POC NT-proBNP, lot 226396	122	−2.6	−1.9	0.98	11.2	0.95

Regression was calculated according to Passing and Bablok: y=a+b×x, with r the correlation coefficient.

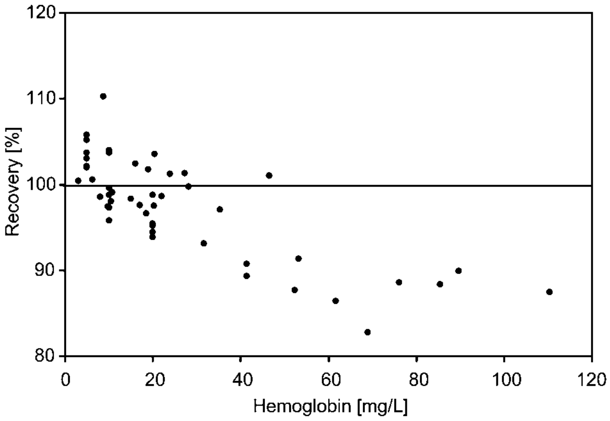

Figure 7 Influence of free plasma haemoglobin on results with POC NT-proBNP. The percentage relative recovery after haemolysis compared to the reference before haemolysis is shown.

Lot-to-lot comparisons

In comparisons of different lots of POC NT-proBNP, all lots showed excellent agreement, demonstrating the reproducibility of the calibration. The differences between the lots ranged from −5% to +4% (Figure 6, Table 3).

Interference testing

The influence of haemoglobin on the POC NT-proBNP test result was within ±7% up to a haemoglobin concentration of 35 mg/L and within ±14% up to 62 mg/L. At higher concentrations (62–110 mg/L), a lower recovery was observed in all samples (n=5), one of which deviated by >15% (Figure 7).

In investigations with biotin of up to 10 mg/L, bilirubin up to 582 μmol/L and rheumatoid factor up to 42 IU/mL (Table 4) no analytical interference was detected, i.e., all deviations from expected values were ≤15%.

Table 4 Interference of biotin, bilirubin and rheumatoid factor with the POC NT-proBNP method.

Interferent	NT-proBNP concentration range, ng/L		
	0–88	89–222	659–1557
Biotin, mg/L			
0, reference	100	100	100
3	<LLMR	90	93
10	<LLMR	92	99
20	<LLMR	84	101
30	<LLMR	83	85
Bilirubin, μmol/L			
0, reference	100	100	100
342	96	99	101
582	93	96	102
Rheumatoid factor, IU/mL			
0, reference	100	100	100
16	<LLMR	89	90
42	<LLMR	97	96
52	<LLMR	93	78
181	<LLMR	66	73

The percentage relative recovery compared to the reference is reported. <LLMR, below the lower limit of the measuring range.

Table 5 Interference of haemotocrit with the POC NT-proBNP method, reported as the relative recovery of NT-proBNP concentrations (measured using the laboratory NT-proBNP method) for the POC NT-proBNP method.

Haematocrit, %	Median recovery, %	n
28–34	101	38
35–44	108	289
45–58	111	43

Table 6 Interference of triglycerides with the POC NT-proBNP method, reported as the relative recovery of NT-proBNP concentrations (measured using the laboratory NT-proBNP method) for the POC NT-proBNP method.

Triglyceride concentration, mmol/L	Median recovery, %	n
0–1.9	106	153
2.0–3.9	107	60
4.0–6.3	89	14

The recovery of laboratory NT-proBNP concentrations according to the POC NT-proBNP test was between 101% and 111% for the haematocrit range studied (Table 5). Moreover there was no correlation between haematocrit and the relative POC NT-proBNP/laboratory NT-proBNP method differences (r=0.16), indicating no influence on the result by haematocrit values between 28% and 58%.

There was no influence of triglycerides at up to 6.3 mmol/L, as demonstrated by recoveries from 89% to 107% (Table 6). The correlation coefficient between triglyceride concentration and the relative POC NT-proBNP/lab NT-proBNP method differences was low (r=−0.05).

The interference of drugs was tested with toxic concentrations of each drug and was repeated with therapeutic concentrations if an influence was found. At therapeutic concentrations, 50 out of the 52 drugs investigated did not influence the POC NT-proBNP result by more than ±15%. With bisoprolol and BNP, somewhat higher bias in the low NT-proBNP concentration range (<175 ng/L) was found, which did not exceed ±33 ng/L in absolute terms (Table 7).

With HAMA serum type 1 and type 2, the recovery was reduced or elevated if MAB 33 was added. Thus, interference from HAMA type 1 and type 2 positive sera was not completely eliminated (Table 8).

Influence of sample volume

There was a slight trend to lower recovery when low sample volumes were applied to the test compared to the regular volume of 150 μL, but overdosing or underdosing by 10 μL did not affect the test result significantly (Figure 8). Insufficient filling of the test strip should be avoided by using a professional laboratory pipette or the POC system pipette supplied by the manufacturer.

Table 7 Interference of drugs with the POC NT-proBNP method.

Drug	NT-proBNP concentration range, ng/L		
	0–106	107–241	864–1519
No drug, reference	100	100	100
Acetaminophen, 200 μg/mL	85	91	93
Acetylcysteine, 150 μg/mL	101	128	118
Acetylcysteine, 30 μg/mL	<LLMR	99	105
Acetylsalicylic acid, 1 mg/mL	108	110	107
Adrenaline, 0.37 μg/mL	<LLMR	84	86
Adrenaline, 0.074 μg/mL	<LLMR	91	97
Ampicillin, 1.0 mg/mL	<LLMR	98	82
Ampicillin, 0.2 mg/mL	<LLMR	106	98
Ascorbic acid, 300 μg/mL	<LLMR	91	96
Bisoprolol, 10 μg/mL	<LLMR	87	83
Bisoprolol, 2 μg/mL	ND	117	107
BNP, 25 μg/mL	<LLMR	123	113
Ca-Dobesilate, 200 μg/mL	<LLMR	87	88
Captopril, 150 μg/mL	108	100	95
Carvedilol, 50 μg/mL	<LLMR	94	98
Cefoxitin, 2.5 mg/mL	87	59	48
Cefoxitin, 0.5 mg/mL	<LLMR	94	95
Cyclosporin, 5 μg/mL	108	101	91
Digitoxin, 0.3 μg/mL	<LLMR	85	93
Digoxin, 0.5 μg/mL	<LLMR	88	91
Doxycyclin, 50 μg/mL	<LLMR	94	98
Enalapril maleate, 40 μg/mL	<LLMR	83	91
Enalapril maleate, 8 μg/mL	<LLMR	99	97
Gentamicin, 0.5 mg/mL	<LLMR	85	83
Gentamicin, 0.1 mg/mL	<LLMR	94	101
Glycerol trinitrate, 192 μg/mL	<LLMR	91	96
Heparin, unfractionated, 5000 U/L	<LLMR	93	111
Heparin, LMW, 29 μg/mL	<LLMR	106	93
Ibuprofen, 500 μg/mL	ND	87	89
Ibuprofen, 100 μg/mL	<LLMR	88	91
Insulin, 840 μg/mL	<LLMR	93	93
Intralipid, 10 mg/mL	<LLMR	92	101
Levodopa, 20 μg/mL	100	100	96
Lidocaine, 100 μg/mL	<LLMR	102	98
Lisinopril dehydrate, 40 μg/mL	ND	107	85
Lisinopril dehydrate, 8 μg/mL	<LLMR	87	100
Lovastatin, 80 μg/mL	<LLMR	81	83
Lovastatin, 16 μg/mL	ND	ND	100
Methyldopa, 20 μg/mL	84	92	101
Methylprednisolone, 80 μg/mL	<LLMR	102	94
Metoprolol, 15 μg/mL	<LLMR	92	88
Metronidazole, 200 μg/mL	102	92	91
Molsidomine, 24 μg/mL	<LLMR	90	108
Nicardipine, 90 μg/mL	<LLMR	96	95
Nifedipine, 60 μg/mL	<LLMR	92	92
Phenprocoumon, 6 μg/mL	<LLMR	90	92
Phenylbutazone, 400 μg/mL	114	91	81
Phenylbutazone, 80 μg/mL	121	106	103
Pravastatin, 40 μg/mL	<LLMR	90	80
Pravastatin, 8 μg/mL	<LLMR	107	100
Propafenone, 900 μg/mL	<LLMR	<LLMR	60
Propafenone, 180 μg/mL	<LLMR	91	97
Propranolol, 0.32 μg/mL	129	109	105
Propranolol, 0.064 μg/mL	<LLMR	99	101
Renin, 205 μU/mL	91	102	86
Reteplase, 1.12 μg/mL	120	106	93
Rifampicin, 60 μg/mL	111	102	92
Simvastatin, 40 μg/mL	ND	115	92
Simvastatin, 8 μg/mL	<LLMR	89	99
Sotalol, 320 μg/mL	<LLMR	106	93
Spironolactone, 400 μg/mL	<LLMR	110	103
Streptokinase, 300 IE	<LLMR	94	107
Theophylline, 1.0 μg/mL	<LLMR	80	85
Theophylline, 0.2 μg/mL	<LLMR	89	94
Tolbutamide, 3 μg/mL	<LLMR	89	91
Torasemide, 200 μg/mL	<LLMR	84	68

(Table 7 continued)

Drug	NT-proBNP concentration range, ng/L		
	0–106	107–241	864–1519
Torasemide, 40 μg/mL	<LLMR	104	90
Urokinase, 34.5 U	<LLMR	101	109
Verapamil, 120 μg/mL	<LLMR	84	100
Verapamil, 24 μg/mL	<LLMR	97	91

The percentage relative recovery compared to the reference is reported. A second, lower therapeutic concentration of a drug was tested if an influence was found with the higher toxic concentration. <LLMR, below the lower limit of the measuring range; ND, not determined.

Table 8 Interference of HAMA sera with the POC NT-proBNP method.

Interferent	MAB 33, mg/mL	NT-proBNP concentration range, ng/L	
		0–60	337–366
HAMA type 1	0, reference	100	100
	0.1	<LLMR	105
	1	<LLMR	100
	10	<LLMR	86
HAMA type 2	0, reference	100	100
	0.1	<LLMR	111
	1	<LLMR	117
	10	<LLMR	99

The percentage relative recovery after addition of HAMA-blocking agent MAB 33 compared to the reference without MAB 33 is reported. <LLMR, below the lower limit of the measuring range.

High-dose hook effect

High NT-proBNP concentrations above the measuring range of the POC NT-proBNP test did not lead to false-negative or false low results due to a potential high-dose hook effect. With NT-proBNP concentrations between 10,000 and 35,000 ng/L, the instrument displayed either ''High >3000 pg/mL'' or an error message. If a quantitative result in this range is needed, the measurement has to be repeated with a laboratory NT-proBNP method.

Conclusions

With the new POC NT-proBNP test, reliable quantitative NT-proBNP results can easily be obtained within less than 15 min. Owing to its excellent analytical concordance with the laboratory NT-proBNP test, we expect a similar diagnostic performance for this assay. The test should therefore be well suited to its intended use as an aid in the diagnosis of patients suspected of having congestive heart failure, in the monitoring of patients with compensated left-ventricular dysfunction, and in the risk stratification of patients with acute coronary syndromes.

A higher level of evidence for its clinical utility may be obtained in clinical studies using the POC NT-proBNP test. Hence, a prospective trial on the efficacy of the POC NT-proBNP test in treatment guidance for chronic heart failure patients in heart failure clinics was designed and is currently ongoing.

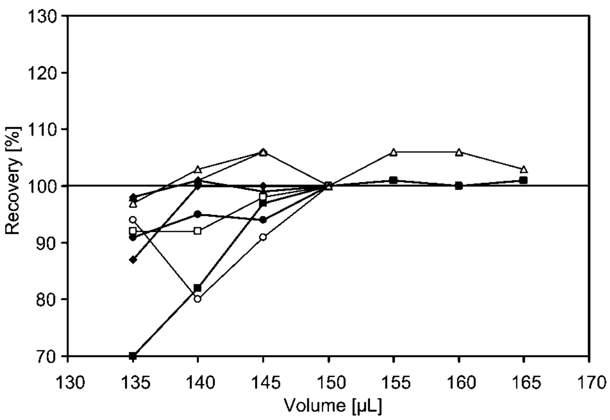

Figure 8 Influence of sample volume on POC NT-proBNP results. NT-proBNP concentrations: ■ 156 ng/L; ● 147 ng/L; ♦ 131 ng/L; ▲ 127 ng/L; □ 144 ng/L; ○ 115 ng/L; ◇ 186 ng/L; △ 1345 ng/L. Mean recoveries of 20 replicates per volume are shown.

Acknowledgements

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Received May 19, 2006, accepted July 7, 2006