2014.08

REF PF1061-KUS IVD For in vitro diagnostic use

PATHFAST® NTproBNP

<REAGENT FOR PATHFAST®>

60 Tests

Intended Use

PATHFAST® NTproBNP is a product for in-vitro diagnostic use with the in vitro diagnostic system PATHFAST® for the quantitative measurement of N-terminal-pro B-type Natriuretic Peptide (NT-proBNP) in heparinized or EDTA whole blood and plasma. The result obtained with the assay is used to assist in the diagnosis and assessment of severity of congestive heart failure (CHF) and risk stratification in patients with acute coronary syndromes (ACS). Measurements of NT-proBNP may also be used to assess increased risk of cardiovascular events and mortality in patients with stable coronary artery disease. PATHFAST® NTproBNP is for use in clinical laboratory or POC settings.

Summary

B-type natriuretic peptide (BNP) is a small peptide (32 amino acids) secreted by heart myocytes to augment regulation of blood pressure and fluid balance. Its pro form ProBNP is synthesized by the left cardiac ventricles as single chain peptide of 108 amino acids. In this process, ProBNP is cleaved into two fragments which are secreted into the bloodstream as the 32 (77-108) amino acids active BNP and the N-terminal fragment of 76 (1-76) amino acids designated as NT-proBNP. Determination of NT-proBNP helps to identify individuals with left ventricular dysfunction. Determination of NT-proBNP helps to identify individuals with left ventricular dysfunction. [1)-5)].

The PATHFAST® NTproBNP is an assay for measurement of NT-proBNP in the format of a chemiluminescent enzyme immunoassay (CLEIA). All required components for performing the testing are packed in one reagent cartridge. By loading PATHFAST® NTproBNP into the in vitro diagnostic system PATHFAST®, NT-proBNP can be accurately quantified within 17 minutes.

Package composition

Reagent cartridge 6 cartridges x 10 trays

The reagent cartridge consists of 16 wells. All wells but sample well (#1) and counting well (#10) are covered with aluminum seal with bar codes on it. All reagents for the test are filled in each well of the reagent cartridge.

Wells	form	Ingredient	Quantity	Source
# 1	Empty	sample well		
# 2	liquid	Alkaline phosphatase conjugated anti NT-proBNP PoAb* MOPS** Buffer	50 μL	Microorganism Sheep
# 7	liquid	anti NT-proBNP PoAb coated magnetic particles MOPS Buffer	50 μL	Sheep
#13	liquid	Chemiluminescent substrate CDP-Star®	100 μL	
# 11	liquid	Sample Dilution Buffer MOPS Buffer	50 μL	
# 3,4,5	liquid	Washing Buffer MOPS Buffer Na azide	400 μL < 0.1%	

*PoAb = Polyclonal antibody**MOPS= 3-Morpholinopropanesulfonic acid

#1,6,8,9,10,12,14,15,16 are empty wells.

CDP-Star® is a registered trademark of Applied Biosystems, LLC.

Calibrators

1.	Calibrator 1 (CAL-1)	2.0 mL x	1 bottle	(liquid)
		Na azide (0.05%)		
2.	Calibrator 2 (CAL-2)	For 1.0 mL x	2vials	(lyophilized)
3.	Calibrator diluent	1.0 mL x	2 bottles	(liquid)
		Na azide (0.05%)		

MC ENTRY CARD 1 sheet

Instruction for use 1 sheet

CONTROL DATA SHEET 1 sheet

Materials Needed But Not Provided

PATHFAST® Analyzer and consumables
NT-proBNP Quality Control Materials

Assay Principle

The PATHFAST® NTproBNP procedure is based on CLEIA and *MAGTRATION®. In this procedure, alkaline phosphatase labeled anti NT-proBNP polyclonal antibody and anti NT-proBNP polyclonal antibody coated magnetic particles are mixed with sample. NT-proBNP contained in the specimen binds to the anti NT-proBNP antibodies forming an immunocomplex with enzyme labeled antibody and antibody coated magnetic particles. After removing the unbound enzyme labeled antibody, a chemiluminescent substrate is added to the immunocomplex. After a short incubation, the luminescence generated by enzyme reaction is detected. The intensity of the measured luminescence is in relationship with the NT-proBNP concentration in the specimen which is calculated by means of a standard curve.

*MAGTRATION® is technology of B/F separation where magnetic particles are washed in pipette tip and is a registered trademark of Precision System Science.

Precautions

Reagents cartridge

1. Do not reuse a reagent cartridge. This is designed for single use only.
2. Do not peel off the aluminum seal.
3. Handle the reagent cartridge by holding the edge of it and do not touch the aluminum seal and the black well with your fingers.
4. Avoid contamination of saliva in the black well.
5. When the reagent cartridge is dropped and damaged, do not use it.
6. Store the reagent cartridges in an upright position at all times.
7. During storage or shipment, there may be some reagents adhering to the aluminum foil. If such a condition is observed, gently tap the cartridge on table before use.
8. Dispose in accordance with applicable national and local institution's regulations. Follow general precautions, and handle all components as if capable of transmitting infectious agents.
9. Avoid contamination and exposure to direct sunlight.
10. Used reagent cartridges contain human body fluids. Handle with appropriate care to avoid exposure to these fluids.
11. Do not use reagents beyond its indicated expiration date.
12. Do not use any reagent cartridge which was left at room temperature over 8 hours.
13. Reagent cartridge contains <0.1% sodium azide, which may react with copper and or led plumbing to form potentially explosive metal azides. When disposing of such reagents and buffers, always flush the disposal area e.g. plumbing with large volumes of water to prevent possible formation of such explosive compounds.

Storage Instructions

Store at +2 to +8 °C. Do not open the cartridge tray prior to use.

Expiration

The expiration date is listed on each reagent cartridge and this reagent package.

Sample Collection

1. Use whole blood or plasma collected with qualified collection tube containing heparin – Na, heparin – Li or EDTA – Na, EDTA – K.
2. Whole blood samples must be analyzed within 4 hours of collection. Immediately before dispensing a whole blood sample into a sample well of a cartridge, the whole blood sample contained in a blood collection tube should be mixed gently (do not use vortex mixer). After dispensing the whole blood sample and loading the cartridge on the PATHFAST®, the assay must be started immediately.
3. It should be ensured that fibrin threads or clots and other insoluble materials are not present in the sample, otherwise such material should be removed by centrifugation or filtrations.
4. Plasma samples may be kept at for 3 months at -20 °C lower until testing is performed. However frozen samples should not be repetitively frozen and thawed prior to testing.

Preparation and procedure

Reagent preparation

1. Reagent cartridge: Ready to use.
2. Calibrator-1 (CAL-1): Ready to use.
   After opening calibrators are stable for the expire date which is printed on the bottle label, if they are stored at +2 to +8 °C
3. Calibrator-2 (CAL-2)
   Reconstitute each vial of CAL-2 with one bottle of Calibrator diluent. Stand for 15 minutes at room temperature after the reconstitution. Mix gently and ensure that the calibrator is completely dissolved. Reconstituted calibrators are stable for 24hr at +2 to + 8 °C or 3 months at –20 °C or lower. Do not exceed three freeze/thawing cycles.

NOTE:

1. Use the same lot of CAL-1, CAL-2, Calibrator diluent and PATHFAST® reagent cartridge. Never mix different lots of CAL-1, CAL-2, Calibrator diluent and PATHFAST® reagent cartridge.
2. CAL-2 contains bovine serum albumin. Handle with appropriate care to avoid skin contact.

Installation of master calibration curve

1. Installation of the master calibration curve is necessary when a new reagent lot is used.
2. Install the master calibration curve by reading the bar code on MC ENTRY CARD, which is enclosed in each package, with the hand-held bar code reader of the PATHFAST®. Refer to the PATHFAST® operator's manual for detailed information.

User calibration
Refer to the PATHFAST® operator's manual.

1. User calibration is necessary when a new reagent lot is used after installation of the master calibration curve on MC ENTRY CARD.
2. User calibration is necessary every **four** weeks after the first user calibration (MC ENTRY CARD is not required).
3. **The calibrators, CAL-1 and CAL-2**, must be tested both in **duplicate**. Therefore four reagent cartridges, two for **CAL-1** and two for **CAL-2** are necessary for user calibration.
4. Set the reagent cartridges in the cartridge rack, then dispense approximately 100 μL of CAL-1 and CAL-2 into the appropriate sample wells and load the cartridge rack onto the PATHFAST®.
5. Carry out user calibration in accordance with the PATHFAST® operator's manual.

Quality Control Assay (QC Assay)

1. Refer to the PATHFAST® operator's manual. A QC assay is performed after every calibration to check the calibration curves and to obtain data from QC samples for quality control. A QC assay is indispensable for assuring validity of sample results. After each calibration, with each new shipment of previously calibrated test kit, or whenever the institution wishes to verify the performance of the system, analyze two levels of quality control material with known concentrations of NT-proBNP.
2. Good laboratory practices recommend the use of appropriate quality controls. It is recommended that federal, state and local guidelines for quality control be followed. If controls do not perform as expected, do not use the test results. Repeat the controls and the test or call your authorized PATHFAST® distributor for technical service.

Sample assay

1. Use heparinized or EDTA whole blood or plasma as sample.
2. Set the reagent cartridge in the cartridge rack, then dispense approximately 100 μL of sample into the appropriate sample well of a cartridge and load the cartridge rack onto the PATHFAST®.
3. Carry out sample assay in accordance with the PATHFAST® operator's manual.

Note:

1. When a whole blood sample is used, the whole blood contained in a blood collection tube should be mixed gently just before dispensing (do not use vortex mixer). After dispensing the whole blood sample and loading the cartridge rack on the PATHFAST®, the assay must be started immediately.
2. When samples are left for more than 5 minutes after dispensing into a sample well, a lower result may be obtained analyzing whole blood because of blood sedimentation and a higher result may be obtained analyzing plasma because of possible evaporation.
3. Samples with result above 30,000 pg/mL can be diluted with sample diluent (Product # PF01D) and retested if a quantitative result is desired or alternatively, the result can be reported as > 30,000 pg/mL.

Expected Values

1. The expected value/reference values may vary from laboratory to laboratory and from country to country depending on various factors. It is therefore recommended that each institution establish its own reference values. The recommended medical decision cutoff value, by age group are;
   Patients < 75 years: 125 pg/mL
   Patients ≥ 75 years: 450 pg/mL

Reference group

Using the PATHFAST® NTproBNP assay, NT-proBNP concentration was determined in 578 individuals without CHF (254 men and 324 women). The statistics for NT-proBNP concentrations in the reference group are shown in the following tables.

All

	< 45 yrs	45-54 yrs	55-64 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	64.1	77.8	153	207	246	98.9
SD	96.0	68.4	555	392	172	289
Median	42.0	56.2	55.4	103	213	52.4
95th percentile	163	229	467	688	604	261
%<125 pg/mL	92.1	80.9	76.8	57.1	-	83.2
%<450 pg/mL	-	-	-	-	87.3	-
N	241	110	99	49	79	499

Males

	< 45 yrs	45-54 yrs	55-64 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	39.4	59.2	74.9	127	224	60.7
SD	29.8	55.0	111	146	135	80.4
Median	30.1	39.1	30.3	64.9	206	35.2
95th percentile	98.4	191	408	603	500	206
%<125 pg/mL	99.0	85.2	84.8	70.0	-	89.6
%<450 pg/mL	-	-	-	-	90.9	-
N	98	54	46	23	33	221

Females

	< 45 yrs	45-54 yrs	55-64 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	81.0	95.7	221	279	262	129
SD	119	75.4	748	515	195	378
Median	55.8	74.2	82.0	142	227	68.2
95th percentile	227	299	757	1994	674	330
%<125 pg/mL	87.4	76.8	69.8	46.2	-	78.1
%<450 pg/mL	-	-	-	-	86.7	-
N	143	56	53	26	46	278

Disease group

Blood samples were obtained from 246 patients diagnosed with congestive heart failure (CHF). The population included 164 men and 82 women. The descriptive statistics and New York Heart Association (NYHA) functional classes are provided below. Each laboratory should establish a reference range that represents the patient population that is to be evaluated. In addition, laboratories should be aware of their institution's current practice for the evaluation of CHF.

All	<45 yrs	45-54 yrs	55-65 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	2651	2026	2890	3268	4684	2649
SD	2794	2855	4531	3779	5140	3675
Median	1676	1059	906	1151	2568	1102
95th	10477	9462	15177	11852	16505	11310
%>125pg/mL	90.0	87.1	92.1	93.5	-	90.5
%>450pg/mL	-	-	-	-	93.6	-
n	20	70	63	46	47	199

Males	<45 yrs	45-54 yrs	55-65 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	2063	2056	3413	3459	4549	2829
SD	2415	2558	5209	3960	4723	3915
Median	1345	1265	1051	1102	2564	1168
95th	8503	7617	17570	11534	16402	11276
%>125pg/mL	81.8	85.1	92.7	90.9	-	88.6
%>450pg/mL	-	-	-	-	90.6	-
n	11	47	41	33	32	132

Females	<45 yrs	45-54 yrs	55-65 yrs	65-74 yrs	75+ yrs	<75 yrs
Mean	3370	1965	1915	2784	4972	2297
SD	3193	3446	2720	3371	6107	3147
Median	3201	609	638	1273	2568	969
95th	10581	12930	10538	12380	21839	11320
%>125pg/mL	100.0	91.3	90.9	100.0	-	94.0
%>450pg/mL	-	-	-	-	100.0	-
n	9	23	22	13	15	67

All	All CHF	NYHA I	NYHA II	NYHA III	NYHA IV
Mean	3038	1486	2968	3302	4373
SD	4064	2275	4429	3805	5017
Median	1466	631	1365	1906	2155
5th	72.5	20.9	78.5	113.6	99.0
95th	12901	5306	14560	12762	14679
% > cutoff	91.1	79.1	92.1	94.5	94.4
Min	9.13	10.4	40.2	9.13	48.2
Max	22778	13078	22778	16258	21839
n	246	43	76	91	36

Males	All CHF	NYHA I	NYHA II	NYHA III	NYHA IV
Mean	3164	1445	3570	3307	3965
SD	4127	2645	5182	3767	3670
Median	1527	631	1339	1906	2553
5th	57.7	22.2	58.4	77.8	279
95th	13182	10560	17295	12706	13217
% > cutoff	89.0	72.0	87.5	93.3	100.0
Min	9.13	18.2	40.2	9.13	279
Max	22778	13078	22778	16258	13217
n	164	25	48	75	16

Females	All CHF	NYHA I	NYHA II	NYHA III	NYHA IV
Mean	2786	1543	1936	3281	4699
SD	3950	1706	2450	4106	5957
Median	1285	754	1365	1639	1921
5th	111	10.4	143	131	51.2
95th	12543	5392	8997	13335	21418
% > cutoff	95.1	83.3	100.0	100.0	90.0
Min	10.4	10.4	142	131	48.2
Max	21839	5392	12572	13335	21839
n	82	18	28	16	20

Specific performance data of the test

Representative performance data on the PATHFAST® is given below.

1. Assay range: 15.0 - 30,000 pg/mL.
2. Methods comparison (plasma samples):
   y = 1.046x + 3.61; r = 0.985, n = 346 (y: this method; x: Roche Elecsys® proBNP)
   Elecsys® is a registered trademark of Roche Diagnostics GmbH.
3. Correlation between whole blood and plasma on PATHFAST®.
   y = 1.040 x - 3.17; r = 0.991; n = 18 (y: heparinized whole blood, x: heparinized plasma)
   y = 1.012 x - 5.32; r = 0.996; n = 18 (y: EDTA whole blood, x: EDTA plasma)
4. Correlation between heparinized and EDTA plasma
   y = 0.961 x – 1.44; r = 1.000; n = 47 (y: EDTA plasma, x: heparinized plasma)
5. Standardization
   The calibrators for PATHFAST® NTproBNP consist of synthetic NT-pro BNP (1-76) provided by Roche Diagnostics GmbH.
6. Imprecision
   Precision was determined using the present method, 4 lithium heparinized plasma-based control materials in a protocol as follows: Four plasma samples were assayed in duplicate for 20 non-consecutive days. The within-run and total standards deviations were calculated according to the NCCLS document EP5-A2 [ISBN 1-56238-542-9]. The following results were obtained;

		Within-run precision		Total precision	
Sample	Mean (pg/mL)	S.D. (pg/mL)	C.V. (%)	S.D. (pg/mL)	C.V. (%)
QC-LL	101	4.14	4.1	4.72	4.7
QC-L	425	13.2	3.1	14.5	3.4
QC-M	2388	97.0	4.1	111	4.6
QC-H	12058	564	4.7	648	5.4

7. Limit of Quantitation: 15.0 pg/mL
   Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a between-run coefficient of variation of 10 %.
8. Analytical specificity
   The following substances have no significant cross-reactivity (less than 1 %) on the assay at the concentration indicated in parentheses on PATHFAST® NTproBNP assay.
   ANP 28 (3.1 μg/mL) NT-proANP 1-30 (3.5 μg/mL)
   BNP 32 (3.5 μg/mL) NT-proANP 31-67 (1.0 ng/mL)
   CNP 22 (2.2 μg/mL) NT-proANP 79-98 (1.0 ng/mL)
   Endothelin (20 pg/mL)

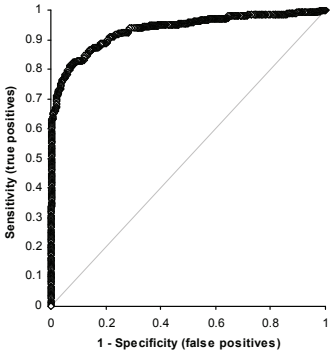
Possible interferences

The following factors were found to have an effect less than 10 % on the assay at the concentrations indicated in parentheses.

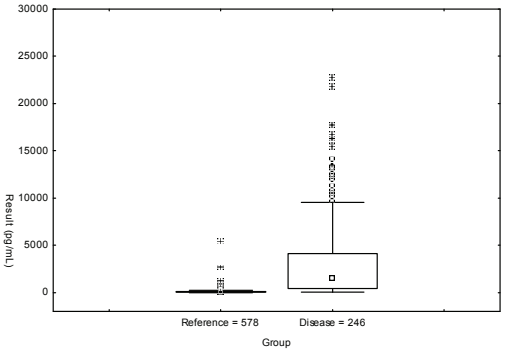
Free bilirubin	(60 mg/dL)
Conjugated bilirubin	(60 mg/dL)
Triglyceride, lipemia in sample	(1000 mg/dL)
Hemoglobin (hemolysis)	(Hb 1400 mg/dL)
Rheumatoid Factor	(1500 IU/mL)

Interpretation of results

The Receiver Operator Curve (ROC) compares clinical sensitivity and specificity at various cut-offs for the 246 patients diagnosed with CHF and 578 subjects without CHF. The ROC for the PATHFAST® NTproBNP assay is presented below. The area under the curve (AUC) for the PATHFAST® NTproBNP is 0.933.



A box and whiskers plot for the clinical study population is presented below. Recommended clinical thresholds are 125 pg/mL for patients younger than 75 years and 450 pg/mL for patients 75 years and older.



Sensitivity and Specificity vs. Age and Gender

The tables below show the clinical sensitivity and specificity of the PATHFAST® NTproBNP assay using a cutoff of 125 pg/mL for patients younger than 75 years and 450 pg/mL for patients 75 years and older.

Males

	<75 yrs	75+ yrs
Sensitivity	88.6%	90.6%
95% Confidence Interval	82.0% - 93.5%	75.0% - 98.0%
Specificity	89.6%	90.9%
95% Confidence Interval	84.8% - 93.3%	75.7% - 98.1%

Females

	<75 yrs	75+ yrs
Sensitivity	94.0%	100.0%
95% Confidence Interval	85.4% - 98.4%	78.2% - 100.0%
Specificity	78.4%	84.8%
95% Confidence Interval	73.1% - 83.1%	71.1% - 93.7%

Age-matched ROC analysis

An age-matched ROC analysis of the clinical data was performed for both the plasma and whole blood NT-proBNP samples utilizing the weighted method described in Kondratovich[6]. The resulting AUC for plasma samples is 0.933 with a 95% confidence interval of 0.921 to 0.944. The resulting AUC for whole blood samples is 0.937 with a 95% confidence interval of 0.927 to 0.948.

Limitations of Procedure

1. The instrument reporting system contains error codes to warm the operator of specific malfunctions. Any report slip containing such error codes should be kept for follow-up. See the PATHFAST® operator's manual.
2. Patient samples may contain heterophilic antibodies that could react in immunoassays to give a falsely high or low result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with cautions.

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Symbols

CE	: EU Conformity
IVD	: For in vitro Diagnostic Use
Lot	: Batch Code
REF	: Product Number
	: Manufactured by
EC REP	: Authorized Representative
Σ	: Contains sufficient for
	: Temperature Limitation
	: Use by
	: Caution, refer to accompanying documents
	: Consult IFU
CAL 1	: Calibrator 1
CAL 2	: Calibrator 2
DILUENT	: Diluent
CARTRIDGE	: Reagent Cartridge
MC ENTRY CARD	: Entry Card for Master Calibration Curve
CONTROL DATA SHEET	: Data Sheet for control

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