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PATHFAST™ NTproBNP

<REAGENT FOR PATHFAST>

60 Tests

English

▪ Intended use

PATHFAST NTproBNP is a product for in-vitro diagnostic use with the in vitro diagnostic (IVD) automated analyser PATHFAST for the quantitative measurement of N-terminal pro-B-type natriuretic peptide (NT-proBNP) in human heparinized or EDTA whole blood and plasma. PATHFAST NTproBNP is intended to be used:

- as an aid in the diagnosis in patients suspected of congestive heart failure (CHF) and detection of left ventricular dysfunction,
- as an aid in the severity assessment of CHF,
- in the risk stratification in patients with acute coronary syndromes (ACS) and CHF,
- for monitoring the therapy in patients with left ventricular dysfunction,
- by laboratory technician, nurse or physician,
- in hospital including emergency room, doctor's office and clinical laboratory.

PATHFAST NTproBNP is a device for near patient testing (NPT).

▪ Summary

B-type natriuretic peptide (BNP) is a small peptide (32 amino acids) secreted by cardiomyocytes 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 non active N-terminal fragment of 76 (1-76) amino acids designated as NT-proBNP. BNP and NT-proBNP is secreted by stretch stimuli to cardiomyocytes caused by an increased intracavitary pressure associated with various cardiac ailments including congestive heart failure (CHF) depending on its severity (1-4).

NT-proBNP with longer half-life than BNP has been reported to be useful in diagnosing heart failure (HF) and detecting left ventricular dysfunction (5-14). 2016 European Society of Cardiology (ESC) Guideline (15) recommended the use of NT-proBNP particularly for ruling out acute and chronic HF, because of its high negative predictive value for diagnosis of HF. NT-proBNP is also useful as an aid in the assessment of the severity and risk stratification in patients with CHF (6, 16-20) and ACS (21, 22). Measurement of NT-proBNP is considered to be useful for therapy monitoring in patients with left ventricular dysfunction (23-26).

▪ Test principle

The PATHFAST NTproBNP procedure is based on chemiluminescent enzyme immunoassay (CLEIA) and MAGTRATION. 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 min (27). In this procedure, alkaline phosphatase labelled anti-NT-proBNP polyclonal antibody (PoAb) and anti-NT-proBNP PoAb coated magnetic particles are mixed with the sample. NT-proBNP contained in the specimen binds to the anti-NT-proBNP antibodies forming an immunocomplex with enzyme labelled antibody and antibody coated magnetic particles. After removing the unbound enzyme labelled antibody, a chemiluminescent substrate is added to the immunocomplex. After a short incubation, the luminescence generated by enzyme reaction is detected. The NT-proBNP concentration in the specimen is calculated by means of a standard curve.

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

▪ Package composition of materials provided

Reagent cartridge 6 cartridges x 10 trays

The reagent cartridge consists of 16 wells. All wells with the exclusion of the sample well (# 1) and counting well (# 10) are covered with an aluminium seal having a bar code. All reagents for the test are filled in each well of the reagent cartridge. Do not reuse a reagent cartridge. This is designed for single use only.

Wells	Form	Ingredient	Quantity	Source
# 1	Empty	Sample well	-	-
# 2	Liquid	Alkaline phosphatase conjugated anti-NT-proBNP PoAb, Triton X-100 (< 0.1%)	50 µL	Micro-organism Sheep
# 7	Liquid	anti-NT-proBNP PoAb coated magnetic particles	50 µL	Sheep
# 13	Liquid	Chemiluminescent substrate, CDP-Star	100 µL	-
# 11	Liquid	Sample dilution buffer Triton X-100 (< 0.1%)	50 µL	-
# 3, 4, 5	Liquid	Washing buffer Na azide (< 0.1%), Triton X-100 (< 0.1%)	400 µL	-
# 1, 6, 8, 9, 10, 12, 14, 15, 16 are empty wells. "CDP-Star" is a trademark or registered trademark of Applied Biosystems, LLC.				

Calibrator 1 (CAL-1)	2.0 mL x 1 bottle (liquid, Na azide < 0.1%)
Calibrator 2 (CAL-2)	For 1.0 mL x 2 vials (lyophilized)
Calibrator diluent	1.0 mL x 2 bottles (liquid, Na azide < 0.1%)
MC ENTRY CARD	1 sheet
Instruction for use	1 sheet
CONTROL DATA SHEET	1 sheet

Materials required but not provided

PATHFAST Analyser (Product #: 300929) and consumables
PATHFAST TIP (Product #: 300936)
NT-proBNP Quality Control Materials
PATHFAST WASTE BOX (Product #: 300950)
PATHFAST SAMPLE DILUENT 1 (Product #: PF01D)

▪ Precautions and warnings

1. Do not peel off the aluminium seal of the reagent cartridge.
2. Handle the reagent cartridge by holding the edge of it and do not touch the aluminium seal or the black well with your fingers.
3. When the reagent cartridge is dropped and damaged, do not use it.
4. Avoid contamination of saliva in the black well.
5. Avoid contamination of foreign substances such as fungi, bacteria and detergent into the specimen.
6. After a certain period of storage or shipment, there may be some reagents adhered to the aluminium seal. If such a condition is observed, gently tap the cartridge on the table before use.
7. Store the reagent cartridges in an upright position at all times.
8. CAL-2 contains human serum. Although the used raw materials were negative for HBs antigen, HIV antibody and HCV antibody, it should be handled as infectious due to a risk of infections.
9. Used reagent cartridges contain bodily fluids. Handle with appropriate care to avoid skin contact and injection.
10. Azide can react with copper and lead used in some plumbing systems to form explosive salts. When disposing of azide-containing materials, they should be flushed away with large volumes of water.
11. Dispose of all measured reagents and materials according to the standard disposal method. For example, autoclave at 121 °C for 20 minutes. Follow general precautions and handle all components as if capable of transmitting infectious agents.
12. The PATHFAST reporting system contains error codes to warn the operator of specific malfunctions. Any reports containing such error codes should be held for follow-up. See the PATHFAST operator's manual.
13. Patient samples may contain heterophilic antibodies that could react in immunoassay 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 caution.
14. The results should be evaluated in context of all laboratory findings and the total clinical status of the patient. In cases where the laboratory results do not match the clinical picture or history, additional tests should be performed.
15. When any serious incident occurs in relation to the product, report to the manufacturer and the competent authority in which the user and/or the patient is located.

Storage and expiration

1. Store at 2 - 8 °C.
2. Store the cartridge tray with the label side up.

3. Avoid water damage during storage.
4. Do not open the cartridge tray until just before use.
5. Avoid contamination and exposure to direct sunlight.
6. CAL-1 can be used until the expiration date after opening.
7. CAL-2 is stable for 2 days at 2 - 8 °C and 3 months at -20 °C or lower after reconstitution.
8. The expiration date is listed on each reagent cartridge and kit box label.
9. Do not use reagents beyond the indicated expiration date.

Sample collection
Use whole blood or plasma collected with qualified collection tube containing Na-heparin, Li-heparin or EDTA.

Sample stability
Whole blood sample must be stored at 2 to 25 °C and analysed within 4 hours after collection.
EDTA and heparinize plasma samples are stable under the conditions below:

2 to 25 °C:	24 hours
-20 °C or lower:	2 months (freeze only once)

Sample volume: 100 µL

▪ Preparation and procedure
Refer to the PATHFAST operator's manual for detailed information of the analyser operation.

Reagent preparation
1. Reagent cartridge: Ready to use.
2. CAL-1: Ready to use. (Limited to use with reagent of the same lot.)
3. CAL-2: Transfer the whole volume of one bottle of calibrator diluent into one vial of CAL-2. Do not use different lots of calibrator diluent to dissolve CAL-2. Stand for 15 minutes at room temperature after the reconstitution. Mix gently and ensure that calibrator is completely dissolved. (Limited to use with reagent of the same lot.)

Installation of master calibration curve
1. Installation of a 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 PATHFAST.

User calibration
1. User calibration is necessary when a new reagent lot is used after installation of the master calibration curve from MC ENTRY CARD.
2. User calibration is also necessary every 4 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, 4 reagent cartridges, two for CAL-1 and two for CAL-2 are necessary for user calibration.
4. Place the reagent cartridges in the cartridge rack, and then dispense approximately 100 µL of CAL-1 and CAL-2 in sample wells to load onto PATHFAST.
5. Push the START button of PATHFAST and perform assay for the calibration.

Quality Control assay (QC assay)
1. QC assay is indispensable for assuring validity of sample results. QC Assay is performed after every calibration to check the calibration curves and to obtain data from QC samples for quality control. After each calibration, with each new shipment of previously calibrated test kit, or whenever the institution wishes to verify the performance of the system, analyse two levels of quality control material with known concentrations of NT-proBNP.
2. Good laboratory practice recommends the use of appropriate quality controls. It is recommended to follow national, federal, and local guidelines for quality control. If controls do not perform as expected, do not use the test results. Repeat the test or call your authorized PATHFAST distributor for technical service.

Sample assay
1. Place the reagent cartridge in the cartridge rack, then dispense approximately 100 µL of sample into a sample well of a cartridge.
2. Load the cartridge rack onto PATHFAST and push the START button of PATHFAST to perform sample assay.

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 a vortex mixer.) After dispensing the whole blood sample and loading the cartridge on PATHFAST, the assay must be started immediately.
2. When fibrin threads or clots and other insoluble materials are present in the plasma sample, such material must be removed by centrifugation or filtration.
3. When samples are left for more than 5 minutes after dispensing into a sample well, a lower result will be obtained analysing whole blood because of blood sedimentation and a higher result will be obtained analysing plasma because of increasing NT-proBNP concentration by evaporation.
4. When a whole blood sample is used, input of an individual haematocrit value of the sample in PATHFAST is optional.
5. Samples with result above 30000 pg/mL should be diluted with sample diluent (Product #: PF01D) and retested if a quantitative result is desired or alternatively, they can be reported as > 30000 pg/mL.

▪ Specific performance data
Representative performance data on PATHFAST are given below.

Metrological traceability
The calibrator for PATHFAST NTproBNP consist of synthetic NT-proBNP (1-76) provided by Roche Diagnostics GmbH.

Precision (repeatability)
Precision was assessed with whole blood and plasma samples at each 3 concentration levels. The samples were tested in 20 consecutive replicates. The following results were obtained.

Whole blood	Mean (pg/mL)	S.D. (pg/mL)	C.V. (%)
Level-1	84.3	4.13	4.9
Level-2	2320	86.4	3.7
Level-3	12104	608	5.0

Plasma	Mean (pg/mL)	S.D. (pg/mL)	C.V. (%)
Level-1	76.5	3.28	4.3
Level-2	2313	99.0	4.3
Level-3	11758	500	4.3

Precision (reproducibility)
Plasma samples at 4 concentration levels within the measurement range were assayed in duplicate in each run, 2 runs per day, for 20 days with 1 reagent lot on 1 instrument, for a total of 40 runs. The within-run and total coefficient of variations (C.V.) were calculated with standard deviations (S.D.) according to the CLSI EP5-A2 protocol. The following results were obtained.

Sample	Mean (pg/mL)	Within-run precision		Total precision	
		S.D. (pg/mL)	C.V. (%)	S.D. (pg/mL)	C.V. (%)
Level-1	101	4.14	4.1	4.75	4.7
Level-2	239	10.4	4.4	11.9	5.0
Level-3	2388	97.0	4.1	120	5.0
Level-4	12058	564	4.7	661	5.5

Analytical sensitivity
Limit of detection (LoD): 4.97 pg/mL
Limit of quantitation (LoQ): 10.4 pg/mL (C.V. 10%)

Linearity
NT-proBNP antigen was spiked into plasma at 3 concentration levels (326, 1514, 11087 pg/mL). The samples were serially diluted with 5-fold using saline and assayed. And one over the assay range level (31591 pg/mL) was serially diluted with 10-fold using saline and assayed. The recovery rate against the theoretical value was within 92 - 105% up to 31591 pg/mL.

Assay range: 15 - 30000 pg/mL
The assay range was set from the results of LoQ and linearity.

High dose hook effect
NT-proBNP antigen was diluted at the concentration of approximately 300000 pg/mL. The samples were serially diluted and assayed. There was no high dose hook effect for the samples with their NT-proBNP values up to 300000 pg/mL.

Analytical specificity
Interference of endogenous substances
The following factors were found to have an effect of less than 10% on the assay at the concentrations indicated in parentheses.

Free bilirubin	(60 mg/dL)
Conjugated bilirubin	(60 mg/dL)
Lipemia	(3000 FTU)
Triglyceride	(1000 mg/dL)
Haemoglobin (haemolysis)	(1400 mg/dL)
Rheumatoid Factor	(1500 IU/mL)

Interference of exogenous substances

The following drugs which might be used in target patients were found to have an effect of less than 10% on the assay at the concentrations indicated in parentheses.

Acetaminophen	(20 mg/dL)	Digoxin	(5 ng/mL)
Acetylsalicylic acid	(0.3 ng/mL)	Dopamine	(65 mg/dL)
Allopurinol	(2.5 mg/dL)	Erythromycin	(20 mg/dL)
Ampicillin	(5 mg/dL)	Furosemide	(2 mg/dL)
Ascorbic acid	(3 mg/dL)	Methyldopa	(2.5 mg/dL)
Atenolol	(1 mg/dL)	Nifedipine	(6 mg/dL)
Caffeine	(10 mg/dL)	Phenytoin	(10 mg/dL)
Captopril	(5 mg/dL)	Theophylline	(25 mg/dL)
Verapamil	(16 mg/dL)		

Cross-reactivity

The following substances have no significant cross-reactivity on the assay at the concentration indicated in parentheses.

Adrenomedullin	(1.0 ng/mL)	Aldosterone	(0.6 ng/mL)
Angiotensin I	(0.6 ng/mL)	Angiotensin II	(0.6 ng/mL)
Angiotensin III	(1.0 ng/mL)	ANP28	(3.1 µg/mL)
Arg-Vasopressin	(1.0 ng/mL)	BNP32	(3.5 µg/mL)
CNP22L	(2.2 µg/mL)	Endothelin	(20 pg/mL)
NT-proANP 1-30	(3.5 µg/mL)	NT-proANP 31-67	(1.0 ng/mL)
NT-proANP 79-98	(1.0 ng/mL)	Renin	(50 ng/mL)
Urodilatin	(3.5 µg/mL)		

Correlation between samples of heparinized plasma and other sample matrices

x	y	n	Slope	Intercept	r
Heparinized plasma	EDTA plasma	47	0.961	-1.44	1.000
	Whole blood	73	1.08	-1.92	0.991

The regression equation was calculated by Passing-Bablok fit.

Method comparison

y= 0.996x + 8.96, r= 0.991, n= 182 (plasma samples, y: PATHFAST NTproBNP, x: Elecsys proBNP, Passing-Bablok fit).

Expected values

1. Reference interval
   The reference interval for the NT-proBNP assay was determined by testing 130 apparently healthy individuals. The 95% interval ranging from the 2.5th to 97.5th percentile was determined to be < 15 - 145 pg/mL.
2. Outpatients with symptoms suggestive of heart failure
   The 2016 ESC guidelines provide a cut off value of < 125 pg/mL for "rule-out" of HF in non-acute settings (15).
3. Patients presenting with acute dyspnoea in the emergency room
   The 2016 ESC guidelines provide a cut off value of < 300 pg/mL for "rule-out" of HF in acute settings (15). Several studies support the values of 450, 900 and 1800 pg/mL for ages < 50, 50 - 75, and > 75 years as "rule-in" cut off values of HF in acute settings (10-11).
4. Association with NYHA classification
   Plasma samples were obtained from 246 patients diagnosed with congested heart failure (CHF). The descriptive studies and New York Heart Association (NYHA) functional classes are provided below.

	All CHF	NYHA I	NYHA II	NYHA III	NYHA IV
MEAN	3038	1486	2968	3302	4373
S.D.	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
% > cut off	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

The expected values/reference values may vary from laboratory to laboratory and from country to country depending on various factors. It is therefore recommended for each institution to establish corresponding expected/reference values. In addition, laboratories should be aware of their institution's current practice for the evaluation of CHF.

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Symbols
LSI Medience Corporation uses the following symbols and signs in addition to those listed in the EN ISO 15223-1:2021 (Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements).

This symbol means "Device for near patient testing".
(Symbols for self-testing and near-patient testing under the IVD Regulation 2017/746/EU. MedTech Europe. Dec. 13, 2018)

: Reagent cartridge

: Calibrator 1

: Calibrator 2

: Calibrator diluent

: Entry card for master calibration curve

: Datasheet for control

* PATHFAST: JP Registered Trademark No.5982733

Summary of safety and performance is available from:
European Database on Medical Devices (EUDAMED).

Contact for technical assistance
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