REF PF1021-K IVD

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PATHFAST™ Myo

<REAGENT FOR PATHFAST>

60 Tests

English

▪ Intended use

PATHFAST Myo is a product for in-vitro diagnostic use with the in vitro diagnostic (IVD) automated analyser PATHFAST for the quantitative measurement of Myoglobin (Myo) in human heparinized or EDTA whole blood and plasma. PATHFAST Myo is intended to be used:

- to assist in the diagnosis and especially in the exclusion of acute myocardial infarction (AMI),
- by laboratory technician, nurse or physician,
- in hospital including emergency room, doctor's office and clinical laboratory.

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

▪ Summary

Myo is a low molecular weight haem protein found in both cardiac and skeletal muscle. Following myocardial necrosis associated with AMI, Myo is one of the first markers to rise above normal levels, increasing measurably above baseline within 2 - 4 hours after infarction, peaking at 9 - 12 hours and returning to baseline within 24 hours. In the absence of skeletal muscle trauma or other situations associated with a non-cardiac related increase in circulating myoglobin (e.g. renal failure), measurement of myoglobin in blood has been used as an early marker of AMI (1-5). Myo can be used as a rapid and sensitive test in the early phase of AMI for its diagnosis in conjunction with the electrocardiogram, CK-MB and cardiac troponin test, and for exclusion of myocardial infarction in patients presenting with acute chest pain (6-9).

▪ Test principle

The PATHFAST Myo 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 Myo into the in vitro diagnostic system PATHFAST, Myo can be accurately quantified within 17 min (10). In this procedure, alkaline phosphatase labelled anti-Myo monoclonal antibody (MoAb) and anti-Myo MoAb coated magnetic particles are mixed with the sample. Myo contained in the specimen binds to the anti-Myo 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 Myo 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-Myo MoAb, Na azide (< 0.1%)	50 µL	Calf intestine Mouse
# 7	Liquid	anti-Myo MoAb coated magnetic particles	50 µL	Mouse
# 13	Liquid	Chemiluminescent substrate, CDP-Star	100 µL	-
# 11	Liquid	Sample dilution buffer Na azide (< 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)	2.0 mL x 1 bottle (liquid, Na azide < 0.1%)
MC ENTRY CARD	1 sheet
Instruction for use	1 sheet

Materials required but not provided

PATHFAST Analyser (Product #: 300929) and consumables
PATHFAST TIP (Product #: 300936)
PATHFAST WASTE BOX (Product #: 300950)
Myo Quality Control Materials
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. Used reagent cartridges contain bodily fluids. Handle with appropriate care to avoid skin contact and injection.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.
14. 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. Calibrators can be used until the expiration date after opening.
7. The expiration date is listed on each reagent cartridge and kit box label.
8. 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 samples must be stored at 2 to 25 °C and analysed within 4 hours after collection.
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, CAL-2: Ready to use. (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 Myo.
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 Myo 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 1000 ng/mL should be diluted with sample diluent (Product#: PF01D) or saline solution and retested if a quantitative result is desired or alternatively, they can be reported as > 1000 ng/mL.

▪ Specific performance data

Representative performance data on the PATHFAST are given below.

Metrological traceability
The calibrator for PATHFAST Myo is traceable to in-house reference material prepared from pure myoglobin from human heart tissue.

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 (ng/mL)	S.D. (ng/mL)	C.V. (%)
Level-1	75.9	3.13	4.1
Level-2	170	5.13	3.0
Level-3	584	17.4	3.0

Plasma	Mean (ng/mL)	S.D. (ng/mL)	C.V. (%)
Level-1	89.0	3.39	3.8
Level-2	188	5.48	2.9
Level-3	562	12.5	2.2

Precision (reproducibility)
Plasma samples at 3 concentration levels within the measurement range were assayed in duplicate in each run, 1 run per day, for 20 days with 1 reagent lot on 1 instrument, for a total of 20 runs. The within-run and total coefficient of variations (C.V.) were calculated with standard deviations (S.D.) according to the CLSI EP5-A protocol. The following results were obtained.

Sample	Mean (ng/mL)	Within-run precision		Total precision	
		S.D. (ng/mL)	C.V. (%)	S.D. (ng/mL)	C.V. (%)
Level-1	23.0	0.676	2.9	0.864	3.8
Level-2	69.1	1.97	2.9	2.30	3.3
Level-3	468	6.38	1.4	10.6	2.3

Analytical sensitivity
Limit of blank (LoB): 0.329 ng/mL
Limit of detection (LoD): 0.456 ng/mL
Limit of quantitation (LoQ): 1.90 ng/mL (C.V. 10%)

Linearity
Myo antigen was spiked into plasma at 3 concentration levels (36.8, 205, 1098 ng/mL). The samples were serially diluted with 5-fold using saline and assayed.
The recovery rate against the theoretical value was within 87 - 110% up to 1000 ng/mL.

Assay range: 5 - 1000 ng/mL
The assay range was set from the results of LoQ and linearity.

High dose hook effect
Sample with Myo antigen concentration of approximately 36000 ng/mL was serially diluted and assayed. There was no high dose hook effect for the samples with their Myo values up to 36000 ng/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	(36 mg/dL)
Conjugated bilirubin	(60 mg/dL)
Lipemia	(3000 FTU)
Triglyceride	(1000 mg/dL)
Haemoglobin (haemolysis)	(1000 mg/dL)
Rheumatoid factor	(500 IU/mL)

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

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

Cross-reactivity
No significant cross-reactivity on the assay for up to 1000 mg/dL haemoglobin.

Correlation between samples of plasma and whole blood

x	y	Anticoagulants	n	Slope	Intercept	r
Plasma	Whole blood	Li-heparin	67	0.988	-0.984	0.993
		Na-heparin	67	0.946	-0.602	0.996
		EDTA-2Na	67	0.981	0.115	0.994
		EDTA-2K	67	0.987	0.949	0.994

The regression equation was calculated by Passing-Bablok fit.

Method comparison
y= 0.650x + 1.73, r= 0.990, n= 138 (plasma samples, y: PATHFAST Myo, x: Stratus CS MYO TestPak, Passing-Bablok fit).

Expected values
Reference interval
The reference interval for the Myo assay was determined by testing 308 apparently healthy individuals. The 95% interval ranging from the 2.5th to 97.5th percentile was determined to be 9.51 to 46.6 ng/mL.

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.

▪ References

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8. Caragher TE, Fernandez BB, Jacobs FL, et al. Evaluation of quantitative cardiac biomarker point-of-care testing in the emergency department. J Emerg Med. 2002; 22(1): 1-7.
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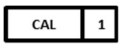
10. Kurihara T, Yanagida A, Yokoi H, et al. Evaluation of cardiac assays on a benchtop chemiluminescent enzyme immunoassay analyzer, PATHFAST. Anal Biochem. 2008; 375(1): 144-146.

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

: Entry card for master calibration curve

* 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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