REF PF1261-KUS **IVD For in vitro diagnostic use**

PATHFAST® hs-cTnI-II

<REAGENT FOR PATHFAST>

60 Tests

Caution: U.S.A Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory and use is restricted to or on the order of a physician. For in vitro diagnostic use only.

Intended Use

PATHFAST hs-cTnI-II is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). PATHFAST hs-cTnI-II is for use in clinical laboratory or point of care (POC) settings.

Summary

Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22,500 daltons. In the heart, troponin I (TnI) together with troponin T (TnT) and troponin C (TnC) forms a troponin complex that plays a fundamental role in the transmission of intracellular calcium signal of actin-myosin interaction. Troponin I is released rapidly to blood circulation 4-6 hours after the onset of AMI and remains elevated for several days thereafter.

The PATHFAST hs-cTnI-II is an assay for measurement of cTnI 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 hs-cTnI-II into the in vitro diagnostic system PATHFAST , cTnI can be accurately quantified within 17 min.

High sensitivity troponin assays have been defined as those which can achieve less than or equal to 10% CV at the 99th percentile of a healthy population and are capable of detecting troponin in greater than 50% of both male and female subgroups.

Package composition

Reagent cartridge 6 cartridges x 10 trays

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

Wells	Form	Ingredient	Quantity	Source
# 2	Liquid	Alkaline phosphatase conjugated anti cTnI MoAb*	50µL	Calf intestine Mouse
		MES Buffer		
		Na azide	< 0.1%	
# 7	Liquid	anti cTnI MoAb* coated magnetic particles	50µL	Mouse
		MOPS Buffer		
#13	Liquid	Chemiluminescent substrate ;CDP-Star	100µL	
# 11	Liquid	Sample Dilution Buffer	50µL	
		Tris Buffer		
		Na azide	< 0.1%	
# 3,4,5	Liquid	Washing Buffer	400µL	
		MOPS Buffer		
		Na azide	< 0.1%	

*MoAb = monoclonal antibody

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

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

Calibrators

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

MC ENTRY CARD 1 sheet
Control Data Sheet 1 sheet
Instruction for use 1 sheet

Materials Needed But Not Provided

PATHFAST Analyzer and consumables
cTnI Quality Control Materials

Assay Principle

The PATHFAST hs-cTnI-II procedure is based on CLEIA and MAGTRATION. In this procedure, alkaline phosphatase labeled anti cTnI monoclonal antibody and anti cTnI monoclonal antibody coated magnetic particles are mixed with sample. cTnI contained in the specimen binds to the anti cTnI 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 cTnI 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 trademark or registered trademark of Precision System Science.

Precautions

Reagent cartridge

1. Do not use reagents beyond its labeled expiration date.
2. Do not reuse a reagent cartridge. This is designed for single use only.
3. Do not peel off the aluminum seal.
4. Handle the reagent cartridge by holding the edge of it and do not touch the aluminum seal and the black well with your fingers.
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. Avoid contamination of saliva in the black well.
8. Avoid contamination and exposure to direct sunlight.
9. 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.
10. 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.
11. Used reagent cartridges contain human body fluids. Handle with appropriate care to avoid exposure to these fluids.
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, cartridge tray and package.

Sample Collection

1. Use whole blood or plasma collected with qualified collection tubes containing only heparin-Li or EDTA-K_2.
2. Heparinized whole blood samples must be analyzed within 4 hours after 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. Heparinized plasma samples may be kept for 4 weeks at -20 ° C or lower until testing is performed. However frozen samples should not be repetitively frozen and thawed prior to testing.
4. When EDTA whole blood or EDTA plasma is used, the assay must be performed within two hours of collection. The values of cTnI in EDTA plasma are approximately 15% lower than those in heparinized plasma after 6 hours of collection.
5. It should be ensured that fibrin clots and other insoluble materials are not present in the sample, otherwise such material should be removed by centrifugation or filtrations.

6. All plasma samples stored longer than 8 hours must be recentrifuged 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 3 days at +2 to +8 °C or 1 month at –20 °C or lower. Do not exceed three freeze/thawing cycles.

   NOTE: 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.

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 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 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 store 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 levels of cTnI .
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 test or call your authorized PATHFAST distributor for technical service.

Sample assay

1. Use anticoagulated whole blood and plasma sample (heparin-Li or EDTA-K_2).
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 50,000 ng/L can be diluted with sample diluent (Product # PF02D) and retested if a quantitative result is desired or alternatively, the result can be reported as > 50,000 ng/L.

High Dose Hook Effect

Patient samples with high troponin I levels can cause a paradoxical decrease in the chemiluminescent intensity (high dose hook effect). In this assay, the PATHFAST results were reported as > 50,000 ng/L when samples above the range of the test were prepared by spiking troponin I antigen purified from human heart muscle into a buffer solution to 44,900,000 ng/L.

Expected values

1. The reference interval for the PATHFAST hs-cTnI-II assay was determined by testing 490 healthy individuals from Northeastern, Southeastern, and Southwestern US. The 99th percentile of the reference interval is 29 ng/L .

Specific performance data of the test

Representative performance data on the PATHFAST are given below.

1. Assay range: 4.1 - 50,000 ng/L (values below 4.1 ng/L reported as <4.1 ng/L).
2. Methods comparison (plasma samples)
   slope＝0.947 (95% CI = 0.891 – 1.004); intercept = –5 (95% CI = –25 to 19), r＝0.994, n＝57（y： PATHFAST hs-cTnI-II , x： Dade Behring Stratus CS cTnI） Range of samples: 100 to 43,450 ng/L.
   Method comparison study (plasma samples) was performed by physician assistants and medical office personnel in three non-laboratory sites. Data was combined with three sites.
   "Stratus CS" is a trademark or registered trademark of Siemens Corporation.
3. Bias between lithium heparin plasma and other sample matrices on 83 samples.

Comparison to lithium heparin plasma:	**Slope (95% CI*)**	**Intercept (95% CI)**
lithium heparin whole blood	0.97 (0.92 – 1.01)	3 (0 – 6)
EDTA-K_2 plasma	0.99 (0.98 – 1.02)	0 (-4 – 10)
EDTA-K_2 whole blood	1.00 (0.96 – 1.04)	3 (-2 – 10)

*CI = Confidence Interval

4. Traceability
   PATHFAST hs-cTnI-II calibrators are prepared from human troponin ITC complex and assigned using internal working calibrators.
   The internal working calibrators' values are based on internal reference materials.
5. Imprecision
   Precision was determined using 4 whole blood and plasma samples representing low (n=2), (n=1), and high (n=1) cTnI levels. The samples were testing in 20 replicates using 3 reagent lots on 1 instrument, and 1 reagent lot on 3 instruments, for a total of 6 different types of runs. The low sample was tested twice, so there were a total of 8 runs. The within-run and total standard deviations were calculated according to the CLSI EP5-A2 [ISBN 1-56238-542-9]. The following results were obtained:

		Whole Blood (ng/L)			
Precision		**LL**	**L**	**M**	**H**
Across Instruments/ within lot	mean	96	930	12,600	38,500
	SD	5	56	427	210
	CV	4.7%	6.0%	3.4%	0.5%
Across lots/ within instrument	mean	96	1,010	12,400	41,300
	SD	7	92	241	2640
	CV	7.0%	9.1%	1.9%	6.4%
		Plasma (ng/L)			
Precision		**LL**	**L**	**M**	**H**
Across Instruments/ within lot	mean	146	924	11,600	30,400
	SD	6	62	762	2,447
	CV	4.3%	6.8%	6.6%	8.0%
Across lots/ within instrument	mean	157	972	12,400	29,700
	SD	17	69	810	480
	CV	10.8%	7.1%	6.5%	1.6%

Precision was determined using 4 plasma samples near the assay's two cutoffs, tested 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 standard deviations were calculated according to the CLSI EP5-A2. The following results were obtained:

		Plasma (ng/L)			
Precision		**#1**	**#2**	**#3**	**#4**
	mean (ng/L)	22	29	86	251
Within-run	SD (ng/L)	1	1	4	9
	CV (%)	6.2	5.1	4.3	3.7
Total	SD (ng/L)	2	2	5	10
	CV (%)	7.1	6.1	5.4	3.9

6. Analytical specificity
Cross reactivity with cardiac troponin T and skeletal troponin I was 0.08% and 0.09%, respectively. Cross reactivity with cardiac troponin C was not detected.
7. Recovery
Plasma samples containing high and low levels of cTnI were mixed at one to one ratio to test recovery. The observed values were then compared to the expected values for each mixture.

Sample Mixture	cTnI Plasma Part 1 (ng/L)	cTnI Plasma Part 2 (ng/L)	cTnI Mix Part 1:Part 2 (ng/L)	cTnI Recovery (%)
A	16	4,690	2,230	94.9
B	120	863	459	93.3
C	120	4,580	2,310	98.4
D	9,320	36,600	22,400	97.7

8. LoB, LoD and LoQ:
LoB, LoD and LoQ were determined using EDTA and lithium heparin whole blood and plasma samples.
LoB was determined using four samples tested in duplicate, 2 runs per day, for 3 days with 4 reagent lots. Each lot had 24 replicates for a total of 96 determinations.
LoD was determined using four low samples tested in duplicate, 2 runs per day, for 3 days with 4 reagent lots. Each lot had 24 replicates for a total of 96 determinations.
LoQ was determined using two sets of 3 samples, each tested on one reagent lot in replicates of four, 3 runs per day, for a total of 12 determinations per sample.
LoD, LoB and LoQ were calculated according to CLSI EP17-A2. The LoQ was determined from the lowest concentration of the sample that had CV of less than 20%. The following results were obtained:

	EDTA (ng/L)		LiHep (ng/L)	
	WB	Plasma	WB	Plasma
LoB	1.466	1.466	1.466	1.466
LoD	2.991	2.958	2.942	3.022
LoQ	4.1	4.1	4.1	4.1

9. Linearity:
EDTA and lithium heparin whole blood and plasma samples were diluted to produce up to 12 dilution levels with values ranging from 1 to 64,500 ng/L. Three-dilution series of each sample matrix were tested across three lots of reagents. Each level was tested in replicates of three.
Linearity was determined according to CLSI EP06 Second Edition.
Linearity was demonstrated across all sample types was 4.1 – 50,000 ng/L at the CV of 20%.

Possible interferences

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)
Triglyceride	(1000 mg/dL)
Hemoglobin (hemolysis)	(Hb 1000 mg/dL)
Rheumatoid Factor	(500 IU/mL)

The following substances were found to have no significant (less than 10%) when added to a plasma pool containing 1,320 ng/L of cTnI at the concentrations indicated below.

Acetaminophen	20 mg/dL	(1320 µmol/L)
Acetylsaltic Acid	0.3 mg/mL	(1.67 nmol/L)
Allopurinol	2.5 mg/dL	(184 µmol/L)
Ampicillin	5 mg/dL	(143 µmol/L)
Ascorbic Acid	3 mg/dL	(170 µmol/L)
Atenolol	1 mg/dL	(37.6 µmol/L)
Caffeine	10 mg/dL	(515 µmol/L)
Captopril	5 mg/dL	(230 µmol/L)
Digoxin	5 ng/mL	(6.4 nmol/L)
Dopamine	65 mg/dL	(3.4 mmol/L)
Erythromycin	20 mg/dL	(273 µmol/L)
Furosemide	2 mg/dL	(61 µmol/L)
Methyldopa	2.5 mg/dL	(118 µmol/L)
Niphedipine	6 mg/dL	(173 µmol/L)
Phenytoin	10 mg/dL	(396 µmol/L)
Theophylline	25 mg/dL	(1390 µmol/L)
Verapamil	16 mg/dL	(0.33 µmol/L)

Diagnosis of AMI – Serial Samples

An additional study was performed on prospectively collected banked serial plasma samples (heparin anticoagulant) from 333 consecutively eligible consented patients presenting to the ER with suspicion of myocardial infarction (MI). The study yielded 72 MI patients and 261 non-MI patients. The blood sample collection times were at 0-2 hours, at 2 to 6 hours, and at 6 to 12 hours of presentation to the ER. The clinical diagnosis of MI was performed by an adjudication panel according to ESC/ACCF/AHA/WHF 2007 guidelines. The adjudication panel used existing clinical data including ECG and other clinical information to make the diagnosis, but not the final discharge diagnosis or the PATHFAST hs-cTnI-II Test results. Clinical sensitivity and clinical specificity were calculated by comparing the PATHFAST hs-cTnI-II Test results to clinical diagnosis assigned by the adjudication panel. The calculations were performed with both the 99th percentile cutoff (≥29 ng/L) and the ROC cutoff (≥264 ng/L) of the assay.

			#/TOTAL	95% CI
Cutoff 29 ng/L	0 to 2 h	Sens	73.6% (53/72)	(61.9% - 83.3%)
		Spec	92.7% (242/261)	(88.9% - 95.6%)
	2 to 6 h	Sens	93.1% (66/72)	(84.5% - 97.7%)
		Spec	93.1% (243/261)	(89.3% - 95.9%)
	6 to 12 h	Sens	91.7% (66/72)	(82.7% - 96.9%)
		Spec	91.6% (239/261)	(87.5% - 94.6%)

			#/TOTAL	95% CI*
Cutoff 264 ng/L	0 to 2 h	Sens	23.6% (17/72)	(14.4% - 35.1%)
		Spec	99.2% (259/261)	(97.3% - 99.9%)
	2 to 6 h	Sens	62.5% (45/72)	(50.3% - 73.6%)
		Spec	98.1% (256/261)	(95.6% - 99.4%)
	6 to 12 h	Sens	80.6% (58/72)	(69.5% - 88.9%)
		Spec	97.7% (255/261)	(95.1% - 99.2%)

Limitations of procedure

1. The instrument reporting system contains error codes to warn the operator of specific malfunctions. Any reports slip containing such error codes should be kept for follow-up. See the PATHFAST operator's manual.
2. Per the current universal definition of MI, the 99th percentile URL should be used as a diagnostic cutoff of AMI. When using the 99th percentile cutoff in clinical settings, PATHFAST hs-cTnI-II should be interpreted using serial cardiac troponin measurements as recommended per current clinical practice guidelines. Due to the release kinetics of cardiac troponin I, an initial test result may not be definitive in diagnosing MI. Serial cardiac troponin measurements are suggested.
Chronic stable elevations of hs-cTnI-II at or above the 99th percentile without a significant rise or fall are common in patients with structural heart disease. Patients with risk factors and persistently elevated cardiac troponin levels in the absence of competing diagnoses may have elevated troponin levels associated with heart failure, angina, acute coronary syndrome, chronic kidney disease, pulmonary embolus, or myopericarditis heart failure.
3. There are reports of autoantibodies to troponin I in the medical literature. Use caution when interpreting a troponin I test result that does not appear to reflect the clinical picture. The PATHFAST hs-cTnI-II assay may be interfered with by these autoantibodies causing a falsely elevated or depressed result.
4. When using the ROC cutoff, the test should be interpreted with 3 serial samples. When samples are collected in the early hours, it is not advisable to use the higher cutoff.

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Symbols

IVD	: For in vitro Diagnostic Use
Lot	: Batch Code
REF	: Product Number
	: Manufactured by
	: 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	: Datasheet for control

*PATHFAST: US Registered Trademark No.3074207

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