



# **Mitsubishi Kagaku Iatron, Inc.**

## ***A Mitsubishi Chemical Company***

### **FOR IMMEDIATE RELEASE**

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### **MKI GAINS CE MARK AND EU APPROVAL FOR 4 KEY CARDIAC MARKERS**

Tokyo, Japan, January 6, 2006 - Mitsubishi Kagaku Iatron, Inc.(MKI), a subsidiary of Mitsubishi Chemical Corporation announced today that it has received marketing approval under the European Union's IVD directive for their Troponin I, creatinine kinase M/B, myoglobin and D-Dimer *in-vitro* diagnostic assays. All four tests were approved to be performed on their PATHFAST™ Point-Of-Care analyzer.

"We are pleased with achieving this important milestone. MKI is now positioned to further enhance it's stance as a global leader in the diagnostic testing market", said Toshihiko Yoshitomi Ph.D., President, Mitsubishi Kagaku Iatron, Inc. "This is only the beginning in our mission to build a unique Point-Of-Care testing platform that will allow the clinician to rapidly test for critical disease states in a near patient setting"

The PATHFAST™ is a compact immunoanalyzer that utilizes patented, CLEIA-MAGTRATION technology. All four tests, Troponin I, Myoglobin, CK-MB and D-Dimer are measured in one batch in 17 minutes utilizing either whole blood or plasma sample. Additional features of the system is that it incorporates an "ALL IN ONE" sealed liquid pre-filled reagent cartridge, which translates into no need for external water supply, drain system, washing buffers or substrate bottles.

Factory calibration can be adjusted by two point calibration at the user's site. The PATHFAST™ system is also equipped with a serial port for bi-directional connectivity with a facilities host computer.

According to the American Heart Association, healthcare expenditure of cardiovascular diseases and stroke in the United States in 2005 is estimated at \$393.5 billion. This figure includes health expenditures (direct costs, which include the cost of physicians and other professionals, hospital and nursing home services, the cost of medications, home health care and other medical durables) and lost productivity resulting from morbidity and mortality (indirect costs)

### **About Mitsubishi Kagaku Iatron, Inc.**

Mitsubishi Chemical Corporation was the first company in the world to market the LPIA, a latex photometric immunoassay device in 1982. In July 2003, Mitsubishi Kagaku Iatron, Inc. was established by merging the former Iatron Laboratories into the diagnostic business group of Mitsubishi Chemical Corporation. Their businesses now include instruments and reagents based on its patented (LPIA) technology, radio immunoassays and a flourishing OEM reagent business. Mitsubishi sees major applications for its technologies as the 'theranostics' sector develops, and has already established links with a number of pre-eminent life science research institutions.

SOURCE: Mitsubishi Chemical America

CO: Mitsubishi Kagaku Iatron

ST: Illinois

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# PATHFAST™

featuring patented Chemiluminescent Magstration® Technology

**MENU**  
**Troponin I**  
**CK-MB**  
**Myoglobin**  
**D-Dimer**  
more to follow...



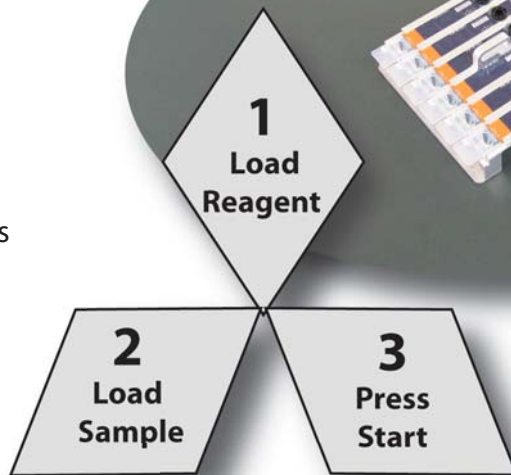
## DESIGNED TO FIT

This full-featured analyzer offers core-lab quality results for a fraction of the cost and space requirements.

## "ALL IN ONE"

Pre-filled, sealed, liquid-reagent cartridges

No need for external water supply, drain system, washing buffers or substrate bottles.



**Six Independent Channels**  
with Results in 17-minutes using  
Whole Blood or Plasma Samples

**Small Yet Powerful**  
Size: 35 x 57 x 50 cm  
Weight: 30 kg

**Easy-to-Use**  
Touch Screen and Built-In Printer

**Bi-directional Connectivity**  
with LIS Using ASTM Standard

## Core-Lab Quality Results for Your Rapid Testing Needs

FDA Pending.  
ID:5501030601.01eu



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