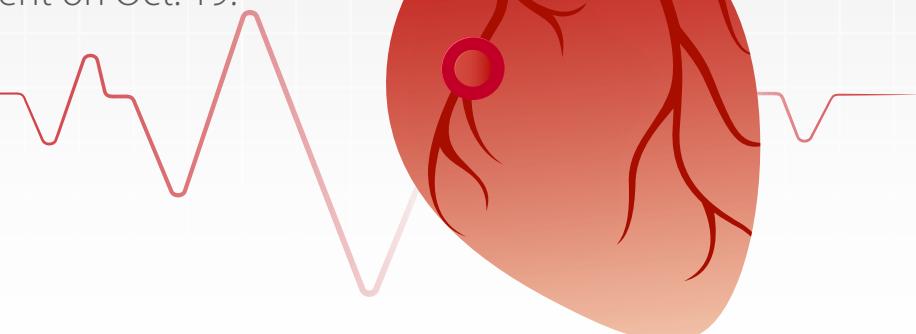


hs-cTnI: Empowering Heart Risk Assessment

Stay tuned for Mindray hs-cTnI & NT-proBNP Assays Online Launch Event on Oct. 19.



Mindray has reinforced its capacity for independent development and production of IVD raw materials with the acquisition of HyTest, a leading global provider of antibodies and antigens situated in Finland. The strategic acquisition has significantly bolstered Mindray's capability to provide cutting-edge immunoassay solutions in various domains, with a particular focus on cardiac disease management.

Strengthened Scientific Research Capabilities in Cardiac Biomarkers

With nearly 30 years of experience, HyTest specializes in developing and supplying world-class antibodies and antigens, particularly in the field of cardiac biomarkers for myocardial infarction and heart failure. Since its foundation in 1994, HyTest has been at the forefront of cardiac biomarker research. In the same year, HyTest introduced its first-generation cardiac troponin I monoclonal antibody, gaining recognition for its exceptional performance.^[1-2]

Pioneering Troponin Research:

HyTest's Quest for Enhanced Cardiac Diagnostics



1994

Founded in Finland



2001

Its myoglobin preparation was selected by the IFCC as an international standard material



2004

Its troponin I-T-C complex was selected by the AACC as a raw material for the international standard



2007

HyTest obtained "patents for method and kit for the diagnosis of troponin I"



2016

Fred Apple, a world-renowned expert on troponin, joined the HyTest Board of Directors to help promote the international standardization of the troponin project

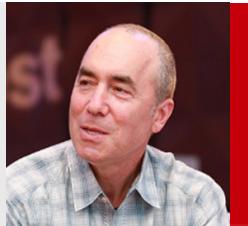


2020

HyTest published 50+ academic articles, with 1800+ citations

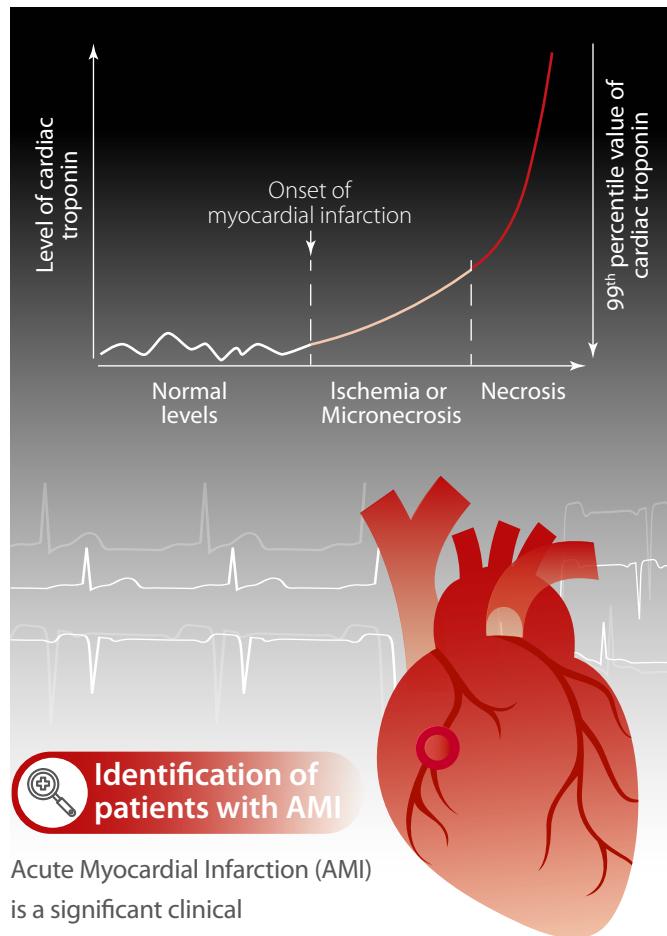


Fred S Apple, PhD



- Chair, IFCC Committee on Clinical Application of Cardiac Biomarkers (C-CB)
- Member, AACC Academy Laboratory Medicine Practice Guidelines on Cardiac Markers
- Chief Scientific Advisor, HyTest

We've been trying to do educational products since the last several years. It's a combination of industry, academic, and hospital-based people. It really works when you put industry together. And one of our focuses is to understand what's going on with troponin, especially high-sensitivity troponin.



Identification of patients with AMI

Acute Myocardial Infarction (AMI) is a significant clinical manifestation of ACS. Per AMI guidelines,^[4] the identification of individuals with AMI involves continuous monitoring of hs-cTnI values. This includes observing fluctuations in the values, with at least one measurement surpassing the 99th percentile URL. Moreover, clinical evidence indicating myocardial ischemia is essential for accurate identification.



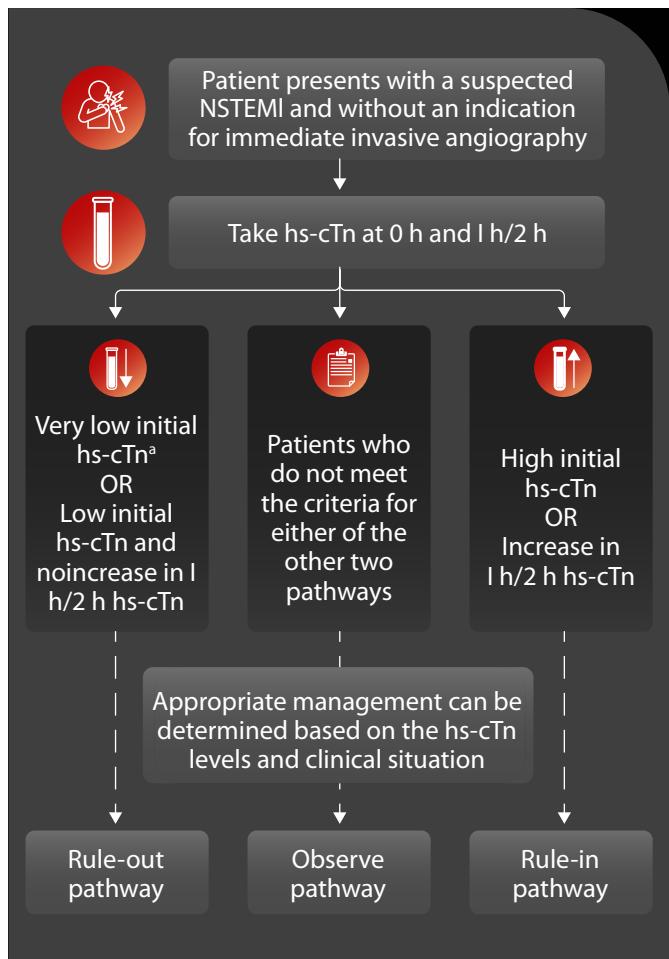
Early diagnosis and rule-out/rule-in of NSTEMI

hs-cTnI testing not only aids in identifying individuals with a high likelihood of AMI but also facilitates the early diagnosis and rapid exclusion of AMI in a significant proportion of patients.

Since 2015, the European Society of Cardiology (ESC) has recommended employing the 0/1h algorithm (preferred) or the 0/2h algorithm (alternative) for swift rule-out and rule-in of Non-ST-segment-elevation myocardial infarction (NSTEMI) type of AMI. Numerous studies conducted in recent years have consistently demonstrated that hs-cTnI values falling below the level of detection yield a negative predictive value (NPV) for AMI exceeding 99%.^[5-6]

hs-cTnI: Empowering Heart Risk Assessment

hs-cTnI, an exceptional assay, earns the "high-sensitivity" label for its ability to detect troponin I in over 50% of seemingly healthy individuals while maintaining a coefficient of variation below 10% at the 99th percentile upper-reference limit (URL). This remarkable sensitivity makes hs-cTnI an essential tool for diagnosing, stratifying risk, and managing acute coronary syndrome (ACS), a subset of cardiovascular diseases (CVDs). CVDs are a leading cause of death worldwide and impose a significant burden on many countries. As per WHO data,^[3] CVDs accounted for 32% of global fatalities in 2019.



ESC algorithms for 0 h/1 h or 0 h/2 h rule-out and rule-in [7]



Differential diagnosis of myocardial injury

Elevated levels of hs-cTnI can also be detected in various other clinical conditions, including acute myocardial injury and chronic myocardial injury.

Similar to the diagnostic interpretation for AMI, acute myocardial injury may require at least one hs-cTnI concentration exceeding the 99th percentile URL, accompanied by a significant dynamic rise or fall pattern.^[8] The critical clinical distinction between these two conditions is the absence of myocardial ischemia symptoms in acute myocardial injury.



Risk stratification and prognosis of patients with ACS

In addition to its diagnostic value in cases of AMI and myocardial injury, serial measurement of hs-cTnI levels,

when combined with existing risk score systems, proves helpful in risk stratification for patients with suspected ACS who are receiving in-hospital care. It also provides valuable prognosis information in terms of short- and long-term mortality. An individual may be considered at intermediate risk based solely on a risk score even if hs-cTnI concentrations are below the 99th percentile. In contrast, the low-risk group can be characterized by hs-cTnI levels that are close to or below the limit of detection (LOD).^[9]

Combining HyTest's advancements in cardiac biomarker research with Mindray's robust R&D capabilities in IVD, we are poised to introduce more cutting-edge products that provide reliable test results for clinical diagnosis. Mindray remains committed to aligning our research with clinical needs and translating scientific breakthroughs into practical applications in the management of cardiac and other diseases.



[Click the link to register for the Global Online Launch](#)

[Event on Oct. 19 to learn more about hs-cTnI:](#)

<https://www.mindray.com/en/events/hs-ctnl-nt-probnp-asays-launch-event>



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