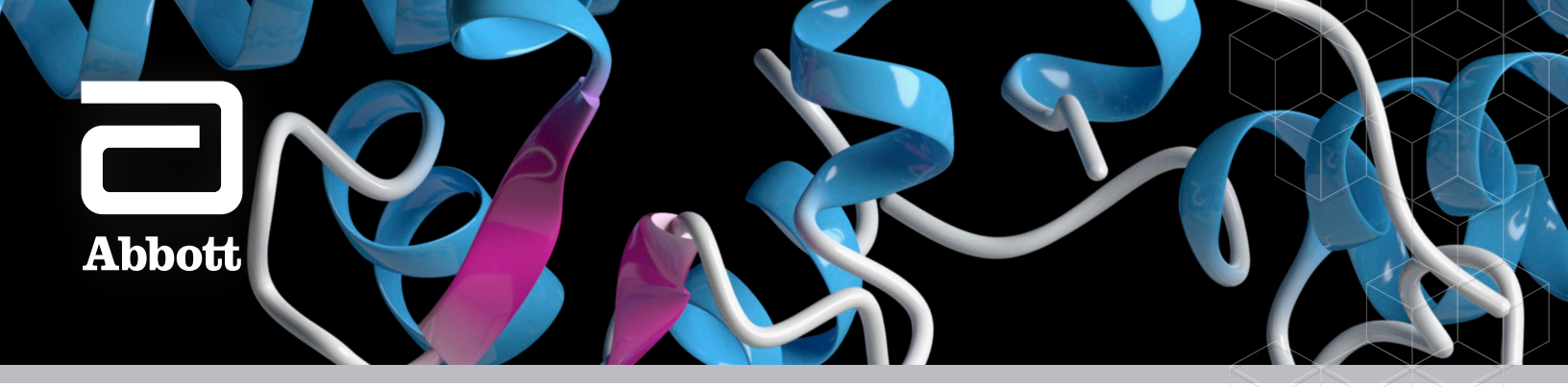

Risk-Stratification of the Apparently Healthy Population for Future Cardiac Events With ARCHITECT High Sensitive Troponin-I

CARDIOVASCULAR RISK – A GLOBAL CHALLENGE: NOW WE CAN HELP IDENTIFY PATIENTS WHO ARE AT RISK EARLIER

422.7 MILLION
The number of prevalent cases of cardiovascular disease around the world in 2015[1]

31.7%
The proportion of deaths projected to be caused by cardiovascular disease by 2030[1]

#1 CAUSE
CVDs are the number 1 cause of death globally: More people die annually from CVDs than from any other cause[2]

RISK-STRATIFICATION OF THE APPARENTLY HEALTHY POPULATION USING CURRENT TOOLS

- Risk Stratification is a tool to help identify and predict patients at high-risk or potentially at high-risk of heart attacks, heart failure or death, and prioritizing their care to help prevent unfavorable outcomes
- Current risk-stratification tools like Framingham, Euroscore and Lipid profile are not cardiac specific and can be heavily influenced by age[3,4]

RISK-STRATIFICATION OF THE APPARENTLY HEALTHY POPULATION USING ARCHITECT STAT HIGH SENSITIVE TROPONIN-I

- The first CE-marked cardiac specific biomarker that aids in predicting future cardiac events using the unmatched power of cardiac specificity[5,6] for a blood test that can be added to existing wellness check offerings
- In conjunction with clinical and diagnostic findings, aids in earlier identification and intervention in higher risk patients to prevent cardiac events[7]
- Compared to existing risk-stratification tools, provides greater accuracy in identifying lower risk patients, which may avoid unnecessary investigations, treatments and potential side effects[7]
- Through early identification and appropriate categorization of at-risk patients,[7] has the potential to reduce the growing cost burden to the healthcare system
- Resistant to biotin interference[8]

INTENDED USE

For *in vitro* diagnostic use only.

The ARCHITECT STAT High Sensitive Troponin-I assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of cardiac troponin-I (cTnI) in human plasma and serum on the ARCHITECT iSystem with STAT protocol capability.

The cTnI values are used as an aid in the diagnosis of myocardial infarction (MI) and to aid in the assessment of 30-day and 90-day prognosis relative to all-cause mortality and major adverse cardiac events (MACE) consisting of myocardial infarction, revascularization and cardiac death in patients who present with symptoms suggestive of acute coronary syndrome (ACS).

The cTnI values may also be used, in conjunction with clinical and diagnostic findings, to aid in stratifying the risk of cardiovascular disease, including cardiovascular death, myocardial infarction (MI), coronary revascularization, heart failure or ischemic stroke in asymptomatic individuals.

VARIOUS STUDIES SUPPORT THE USE OF ARCHITECT STAT HIGH SENSITIVE TROPONIN-I AS A RISK-STRATIFICATION TOOL:

- A statistically robust association between baseline concentrations of circulating cardiac TnI, as measured by a high-sensitivity assay, and the occurrence of major vascular events and death was determined in 12,956 participants with normal cholesterol levels and no prior cardiovascular disease[9]
- In 74,738 participants, the addition of troponin-I to conventional risk factors improves risk prediction in particular for cardiovascular death as well as any first cardiovascular event and overall mortality in the general population[10]
- Troponin concentrations are reduced by statin therapy, and reductions in troponin concentrations are associated with better outcomes independent of LDL cholesterol lowering[11]
- Concentrations of hs-TnI were more strongly associated with admission for AMI, HF or cardiovascular death than concentrations of hs-CRP[7]

The following cut-off points may be used to aid in stratifying the risk of cardiovascular disease in asymptomatic individuals:[6]

TROPONIN LEVEL		
Risk	**Male (pg/mL)**	**Female (pg/mL)**
Low	<6	<4
Moderate	≥6 – ≤12	≥4 – ≤10
Elevated	>12	>10

Asymptomatic individuals with elevated troponin levels are associated with a higher risk of developing cardiovascular related diseases in the future.[6]

TROPONIN USE IN ASYMPTOMATIC GENERAL POPULATION VS. IN THE EMERGENCY DEPARTMENT

	EMERGENCY DEPARTMENT (ED)	NON-EMERGENCY DEPARTMENT (NON-ED)
Population Tested	Symptoms suggestive of Acute Coronary Syndrome (e.g., Chest pain, shortness of breath, nausea, dizziness)[12]	No symptoms (Asymptomatic)
Use	In conjunction with clinical and ECG findings, used in Emergency Department to aid in the diagnosis of heart attacks[13] (Urgent)	In conjunction with clinical, diagnostic findings and existing tools like Framingham 2008[14] and SCORE,[15] aid in stratifying the risk of cardiovascular disease, including cardiovascular death, myocardial infarction (MI), in asymptomatic individuals[6] (Non-Urgent)
Test Prescriber	ED Physician, Cardiologist	Primary Care Physician, General Practitioner, Internist, Preventative Cardiologist
Test Setting	Hospital Laboratory	Hospital/Private/Reference Laboratory
Clinical Value	Troponin results are crucial to helping physicians identify which patients who come to the Emergency Department with symptoms are actually having a heart attack vs. experiencing other medical conditions[16]	Troponin results aid physicians in earlier identification and intervention to help prevent cardiac events. The test aids in the stratification of patients' risk of future cardiovascular disease, including heart attacks, heart failure or death (low, moderate or elevated)[6,7]

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SPECIFICATIONS[6,17,18]

ARCHITECT STAT hsTnI SPECIFICATIONS	
Method and Format	Two-step CMIA Assay with STAT protocol capability
Result Unit	pg/mL; alternative SI unit = ng/L
Measuring Interval	3.2 ng/L to 50,000 ng/L
Time to First Result	STAT 18 min
Control Concentration Levels*	Low: 20 ng/L; Range = 12.0-28.0 ng/L Medium: 200 ng/L ; Range = 120.0-280.0 ng/L High: 15,000 ng/L ; Range = 9,000.0-21,000.0 ng/L
Limit of Quantitation (LoQ)	≤3.2 ng/L†
Limit of Detection (LoD)	LoD ranged from 1.1 to 1.9 ng/L
Limit of Blank (LoB)	LoB ranged from 0.7 to 1.3 ng/L
99th Percentile; Precision at the 99th Percentiles	Overall = 26.2 ng/L 4.0%CV; Females = 15.6 ng/L 5.3% CV Males = 34.2 ng/L 3.5% CV
Precision Below LoQ	10% CV = 4.7 ng/L 20% CV = 1.3 ng/L
Specimen Type	**Serum**: With and without separator; serum with thrombin-based clot activator **Plasma**: Lithium Heparin with and without separator; K2 EDTA and K3 EDTA
Sample Volume	Priority: 210 µL for the first test plus 160 µL for each additional

*Contact your local Abbott representative for additional available controls
†The data still supports a Limit of Quantitation (LoQ) of less than or equal to 10pg/mL at 10%CV

ORDERING INFORMATION

PRODUCT DESCRIPTION		LIST NUMBER
ARCHITECT STAT hsTnI Reagent	100 Test Kit	3P25-27
	500 Test Kit	3P25-37
ARCHITECT STAT hsTnI Calibrators (6 levels, A-F)		3P25-02
ARCHITECT STAT hsTnI Controls		3P25-11
ARCHITECT i Multi-Assay Manual Diluent		7D82-50
ARCHITECT STAT hsTnI e-Assay File	Available on corelaboratory.abbott	

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