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National Horizon Scanning Unit
Horizon scanning prioritising summary

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I-STAT® Cardiac Troponin I (cTnl) test: for the assessment of biomarkers for acute myocardial infarction in patients presenting to emergency departments.

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PRIORITISING SUMMARY

REGISTER ID: **000092**

NAME OF TECHNOLOGY: **I-STAT® CARDIAC TROPONIN I (CTNL) TEST**

PURPOSE AND TARGET GROUP: **ASSESSMENT OF BIOMARKERS FOR ACUTE MYOCARDIAL INFARCTION FOR PATIENTS PRESENTING TO EMERGENCY DEPARTMENTS**

STAGE OF DEVELOPMENT (IN AUSTRALIA AND/OR NEW ZEALAND):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	73566
☐	No	☐	Not applicable

The I-STAT System Analyzer is available in over 400 sites in Australia for other blood testing applications.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

IMPACT SUMMARY:

The I-STAT Corporation provides the I-STAT® Cardiac Troponin I (cTNL) test with the aim of assessing Troponin I levels (in heparinised whole blood or plasma samples) in patients with chest pain presenting to Emergency Departments. The manufacturer states it can be used in the diagnosis and monitoring of acute myocardial infarction and in assessing the risk of mortality.

The I-STAT® test is contained in a single test cartridge and is used with the I-STAT System Analyzer. The cartridge containing the blood sample is inserted into the I-STAT Analyzer and levels are measured automatically. The I-STAT Analyzer is not a new device: it is currently used for other blood testing.

BACKGROUND

Elevations of blood serum Troponin T and I values may be used to rule out acute myocardial infarction (AMI) before discharging patients from emergency departments.

A systematic review of Troponin T and I levels for diagnosing AMI in Emergency Departments included eleven level I criteria (prospective studies of patients, diagnosed with WHO criteria for AMI, and assessment blinded to Troponin results) and an additional 8 level II criteria (as level I but nonconsecutive or unspecified) studies. Diagnostic sensitivity and specificity for different points in time from patient arrival in Emergency Department or from onset of pain are presented in this review (Ebell et al. 2000). The review concluded that sensitivity to Troponin T and I increases from 10% to 45% within one hour of the onset of pain to more than 90% at eight or more hours. Specificity declines gradually from 87% to 80% from 1 to 12 hours after the onset of chest pain for Troponin T and is approximately 95% for Troponin I after 1 to 12 hours. The authors conclude that the use of Troponin T and I as biomarkers of AMI needs to be interpreted according to the number of hours from onset of pain. Currently, manual testing of Troponin I biomarkers takes over one hour, the advantage of the I-STAT® Cardiac Troponin test is that it is performed at point of care and produces a result in 10 minutes.

CLINICAL NEED AND BURDEN OF DISEASE

In Australia 7,484 males and 6,959 females died from AMI (777.1 and 711 per million people respectively) in the year 2001 (AIHW 2004). There were 40,338 hospital separations by principal diagnosis in ICD-10-AM for AMI in 2001-02.

DIFFUSION

Troponin testing for AMI is currently conducted in hospital laboratories in Australia (Davey, 2003). The I-STAT (cTNL) test cartridges were recently introduced to Australia in March 2004 (personal communication, I-STAT corp. company spokesperson). Given that Troponin testing is standard in Australian hospitals for diagnosing AMI, the increased speed of acquiring results through an I-STAT Analyzer compared to standard laboratory testing, suggests that the uptake of the I-STAT (cTNL) test cartridges will be quick.

COMPARATORS

Until recently the World Health Organisation criteria for diagnosing AMI included elevation of creatine kinase (CK), myocardial bound creatine kinase (CK – MB) blood levels, along with electrocardiographic changes and a clinical history compatible with ischaemia. The measurement of total CK is no longer recommended for the routine *diagnosis* of AMI, because of the wide tissue distribution of this enzyme.
The protocols for AMI were revised and consensus guidelines from the American Heart Association, American College of Cardiology and European Society of Cardiology have endorsed the use of serum or plasma cardiac Troponins for the diagnosis of AMI (Antman et al 2000, Jaffe et al. 2000).

The revision of guidelines for biomarkers in diagnosing AMI states that cardiac Troponin (I or T) is the preferred biomarker for myocardial damage due to its nearly absolute specificity, as well as high sensitivity, thereby reflecting even microscopic zones of necrosis of myocardial tissue. The protocols suggest that negative Troponin levels measured at 6 hours after symptom onset and again at 12 hours can safely determine whether a patient's symptoms are caused by an AMI (Antman 2000, Wu 1999).

The I-STAT test is the first point of care test that provides rapid measurement of Troponin I blood levels in 10 minutes. The standard method of measuring Troponin I in patients presenting in Emergency departments is to analyse blood samples in a hospital laboratory: this method can take up to and over one hour.

COST IMPACT

The current costs of pathology testing for creatine kinase, Troponin or myoglobin testing in plasma or serum for MBS item numbers 66518 and 66519, are $20.40 and $40.85. The cost of the I-STAT cartridge is approximately $15.00.

EFFECTIVENESS AND SAFETY

There were no studies available that assessed the effectiveness or safety of the I-STAT® test. Information from the American Food and Drug Administration approval process refers to clinical testing undertaken at three clinical sites comparing the I-STAT cTnl test with another Troponin test, the Stratus CS. This reports that the lower limit of detection for the I-STAT method is slightly lower at 0.02ng/ml versus 0.03ng.ml for the Stratus method. There appear to be no reports of the I-STAT cTNL compared to other Troponin tests.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

CONCLUSION:

There is a lack of evidence on the use of the I-STAT cTNL. In addition, it is considered that this technology doesn't differ sufficiently from existing technologies already in use.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:

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Zarich, S. W.,Bradley, K.et al (2004). 'Minor elevations in Troponin T values enhance risk assessment in emergency department patients with suspected myocardial ischemia: analysis of novel Troponin T cut-off values', *Clin Chim Acta,* 343 (1-2), 223-229.

SEARCH CRITERIA TO BE USED:

Biological Markers/blood
Chest Pain/diagnosis
Coronary Disease/blood/ diagnosis
Myocardial Infarction/ diagnosis
Troponin I/ blood