Health Technology Review	
Technology Ref.:	HTA23005
Technology Name:	Elecsys Troponin T hs, Elecsys Troponin T hs STAT (0/1 hour algorithm)
Approvals by International Bodies:	FDA, CE Mark and MoHaP
Company name:	Roche Diagnostics
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Short Description of the Technology:	**Elecsys Troponin T hs, Elecsys Troponin T hs STAT (0/1 hour algorithm)** is an immunoassay for the in vitro quantitative determination of cardiac troponin T in human serum and plasma. This assay can be used as an aid in the differential diagnosis of acute coronary syndrome to identify necrosis, e.g. acute myocardial infarction (AMI), and as an aid for early discharge and outpatient management for patients suspected of acute coronary syndrome (ACS). The test is further indicated for the risk stratification of patients presenting with acute coronary syndrome and for cardiac risk in patients with chronic renal failure. The test may also be useful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac troponin T (cTnT). In addition, this test can be used in the context of non-cardiac surgeries to predict pre-operatively the perioperative risk of major adverse cardiac events and in diagnosis of perioperative myocardial infarction (PMI) and myocardial injuries after non-cardiac surgeries (MINS). The cTnT-hs values may also be used, in conjunction with clinical and diagnostics findings, to aid in stratifying the long-term risk of cardiovascular death, myocardial infarction, coronary revascularization, heart failure or ischemic stroke, and all-cause mortality in asymptomatic individuals. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The test is highly recommended by several well stablished International Bodies such as; FDA and CE Mark. High-sensitivity troponin test is recommended for early rule out of acute myocardial infarction, so most emergency departments implemented early rule-out strategies as quick, accurate tests may reduce anxiety for patients and healthcare providers.

Advantages	**Disadvantages**
FDA approved, CE Mark and MoHaP	For professional use only
Results are available in 18 minutes with the standard test and in 9 minutes with the STAT test	False results can occur due to interference from other substances in the blood
No risk to healthcare professional & patients	
Estimates of sensitivity and specificity, using a single sample and a limit of detection threshold, were 99% (95% CI 97 to 99) and 36% (95% CI 28 to 45) respectively, based on data from 9 studies done by NICE.	
Enables timely clinical management decisions, as well as appropriate disease control measures	
Highly recommended by NICE, as options for the early rule out of non-ST-segment elevation myocardial infarction (NSTEMI)	
Evidence shows that, it's cost effective compared with standard troponin tests in different early rule-out test strategies (NICE)	
Can detect lower levels of troponin in the blood earlier than standard troponin tests, this could lead to fewer people being admitted to hospital, earlier discharge for people with normal troponin levels and earlier intervention for those with a confirmed NSTEMI.	

We recommend an **approval of using this technology** with the following conditions:

1. To be used in a laboratory setting by health care professional.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "Elecsys Troponin T hs, Elecsys Troponin T hs STAT (0/1 hour algorithm)"

- **Population/ Intended User**;
- **To be performed by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Laboratories
- **Condition of use:**
  - Patients presenting to the ER with chest pain
- **Exclusion criteria:**
  - Other conflicting medical issues