



Health Technology Review

Technology Ref.:	HTA22027
Technology Name:	PULS Cardiac Test
Approvals by International Bodies:	CAP & CLIA Certified Lab in the USA
Company name:	Morningstar Laboratories, LLC
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Short Description of the Technology:	<p>The PULS Cardiac Test should be performed on a serum and EDTA plasma sample. Patients do not need to fast for the test. The PULS Cardiac test score is based on permutations of biomarkers and global risk factors that identify the asymptomatic, or vulnerable patient. This is an algorithmic test that more accurately reclassifies intermediate risk patients to either low or high risk. The PULS Cardiac Test is diagnostic for endothelial injury, identifies residual risk, and is predictive of ACS within a 5-year period. PULS Cardiac Test results provide a personalized 5-year Cardiac Profile score that conforms to ACC/AHA Guidelines for Normal, Borderline, or Elevated Risk:</p> <ul style="list-style-type: none"> • Normal (<3.5%): These patients are in the desired range. Reviewing good nutrition and exercise habits and identifying any areas of concern like heart age, rising BMI or family history will dictate if additional recommendations are encouraged. • Borderline (3.5-7.49%): Patients in the intermediate range are generally early in disease progression. Frequently, simple lifestyle modifications such as a healthy diet, physical activity, smoking cessation, and stress management can bring these individuals back into the normal range. • Elevated (>7.5%): These patients have an elevated risk of ACS and should be treated as such using the ACC/AHA guidelines. Further evaluation is recommended to better define the clinical picture and treatment plan. If the patient is not currently under the care of a cardiologist, referral to a cardiologist should be considered. Case studies have shown that some patients with high-risk results who have not acted on the information have experienced heart attacks within weeks or months of the test.
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Health Technology Assessment Team Recommendation:	Disapprove
Summary of Review:	



The PULS Cardiac Test measures protein markers in the blood that are linked to unstable plaque to see if a heart attack may be likely in the next five years. It allows to understand the risk for a vulnerable plaque rupture, and more importantly allow to help reverse the disease risk. The test taken if the patient has one or more risk factors for coronary heart disease such as (a family history of early heart disease, a poor diet/lifestyle, elevated LDL cholesterol, high blood sugar or diabetes, high blood pressure, you are overweight or obese, or exposed to toxins).

Advantages	Disadvantages
A good diagnostic tool to define the higher risk for a heart attack in the next five years in symptomatic patients.	Recommendation and guidelines; do not have any recommendations by international reputed clinical societies and international clinical practice guidelines for using this diagnostic tool in routinely fashion.
Safe & Easy to conduct; Does not require fasting or special preparations.	Efficacy; Limited evidence on the efficacy of the Test
Patient quality of life; Conducting the Puls cardiac test enable preventive action at an early stage of disease progression, when it is most effective to improve patient care and potentially prevent death or disability.	International approvals; There is an alternative test: Lp-PLA2 - a test that measures serum lipoprotein-associated phospholipase A2 (Lp-PLA2) for the assessment of coronary heart disease (CHD) risk in patients without existing disease which is approved by FDA and has excellent supporting studies
Accreditation; The Morningstar Laboratories, LLC in USA where the test analysed are CAP & CLIA Certified	Data Safety; The test analysed outside UAE which raise the Risk of patient data leak
Predictive and prevention: Blood test designed to help identify people who appear healthy but may have active heart disease which could result in a heart attack. This test detects the early stages of heart disease by recognizing blood vessel injury and unstable plaque formation, even in patients who otherwise have no signs or symptoms	

We recommend a **Disapproval of using this technology** due to lack of efficacy and it does not have any recommendations from any international guidelines.

Technology Image

